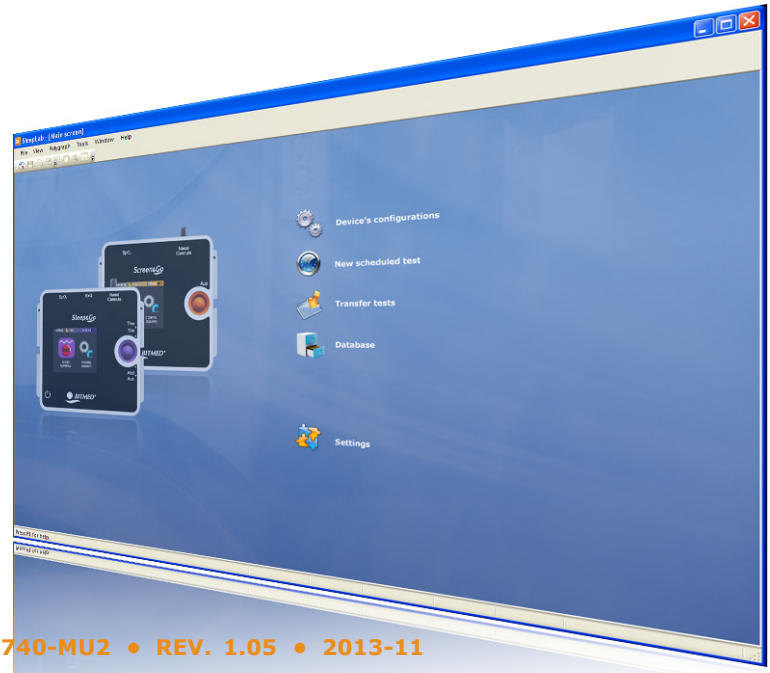
BitmedLab

SCREENING OF SAHS

CARDIORESPIRATORY POLYGRAPHY

POLYSOMNOGRAPHY

USER'S MANUAL



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BitmedLab User's Manual
Revision: 534-740-MU2 Rev. 1.05
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This manual can be purchased from the Technical Assistance Service.

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• The locale where the appliance is installed or used meets the requirements for IEC electrical installation, as well as all other regulations that might pertain.
• The repairs, revisions or modifications, both within and without the warranty period are performed by MEDITEL Ingeniería Médica S.L. or SIBEL S.A. technical personnel.
• The product is used by qualified personnel and according to the recommendations made in this User's Manual.

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Bitmed is a registered trademark of Sibel, S.A.
Windows is a trademark of Microsoft Corporation.

PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE DIRECTIVE 93/42/EEC (CLASS IIa).

CE 0197

Thank you for choosing this product. The BitmedLab software is designed and manufactured with the best guarantees of quality.
Applications of BitmedLab software will open a world of possibilities in the sleep study.
If you have any possible improvement for this product, we welcome your suggestions may be directed to Customer Service Department.

Revised	Approved
Date: 2013-11	Date: 2013-11
Technical Director	Sales Director

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1. INTRODUCTION

BitmedLab software has been designed and manufactured according to the SIBEL S.A. Quality Manual. This Manual complies with quality standards EN 13485 and ISO 9001, as well as with European Medical Device Directive 93/42/EEC According to this directive, this device is Class IIa.

1.1 WHAT IS BITMEDLAB SOFTWARE?

BitmedLab software is the interface between the sleep study systems (Bitmed Screen&Go, Bitmed Sleep&Go, Bitmed eXea PSG) and the user via a PC.

BitmedLab provides review and analysis of holter and real time tests performed by Bitmed product line systems.

Bitmed product line systems are delivered with all their accessories and with BitmedLab analysis software. This manual describes the BitmedLab software.

Please read this manual carefully before using the BitmedLab software, especially those sections marked with an exclamation mark.

BitmedLab software consists of two different modules that vary depending on the systems they support and the functionalities they offer:

SleepLab: module to be used with the screening systems and Screen&Go and Sleep&Go polygraphs.

SleepLab Pro: specialized module for the study of sleep disorders with the eXea system.

The two modules are distributed as the BitmedLab suite.

The manual covers aspects of the program that are common to all the modules, as well as individual features of each module. If you already have a Screen&Go/Sleep&Go, read chapters 1, 2, 3 and, optionally, chapters 5 and 6. On the other hand, if you already have

an eXea system, read chapters 1, 2, 4 and, optionally, chapters 5, 6 and 7.

1.2 INTENDED USE

Acquisition, storage, display and analysis of biomedical sleep signals for diagnosis and control of sleep disorders (Sleep Related Breathing Disorders, Restless Leg Syndrome and Periodic Limb Movement Disorder).

Next conditions must be taken into account:

- Use in a health center.
- Not intended for monitoring vital signals.
- EKG signal can not be used for heart diagnosis purpose. It's only intended for bradycardia and tachycardia detection during sleep analysis.

1.3 INDICATIONS FOR USE

The BitmedLab software has been designed for being used by a doctor or a technician trained in the acquisition of cardiorespiratory signals, in the transmission and visualization of the data in the Personal Computer, and in the analysis of the signals. Therefore, it is not recommended change the configuration of the device without understanding the principles of signal digitalizing.

Minimum age of patients is 5 years, weighing over 15 kg and a minimum height of 70 cm. The medical staff will instruct the patient for a correct test execution, to avoid interferences in the measurement and to replace the sensors in case of movement. It is therefore important that the patient can understand the instructions given by medical staff.

The intended environments of use are hospitals, sleep centres and sleep clinics. Tests may also be carried out at the patient's home, with the exception of ExG signals (EEG, EMG, EOG, EKG). In this case the patient is only authorized to start and stop the test, and should be adequately instructed by the doctor on this respect.

Using the BitmedLab software does not involve any monitoring or diagnosis of the patient.

1.4 SAFETY PRECAUTIONS AND RECOMMENDATIONS

The manufacturer is liable for the safety, reliability and operation of the devices only if the following points are observed:

- For correct system operation, BitmedLab software should be used only with the devices listed in the section above. Please read the user's manual of your system before using it.
- Use the device according to the instructions included in the device manual.
- Liability does not cover the effects derived from the use of the software or the device it is connected to.
- The manufacturer or an Authorized Assistance Center performs modifications or repairs.
- The system is used according to the instructions of use.
- The computer, monitor and accessories where the software is used, meet the low voltage Directive (particularly EN60950 standard) and EMC Directive (particularly EN55022, EN61000-3-2, EN61000-3-3 and EN55024 standards).
- Verify your operating system is properly installed and updated.
- Verify that the hardware of your PC works properly.
- To comply with Medical Devices Directive 93/42/EEC and for safety and reliability purposes, ensure that the device and its software are used by personnel that are adequately trained in the intended use of the device.

The software BitmedLab runs on PC. Make sure you save the test or changes made before turning off the PC. Do not turn off the PC when performing a real-time test. Stop the real-time test first.

Check if software updates are available.

Although the CDs can bear temperatures over 70 º C, the information stored could be lost if exposed to high temperatures for a long period of time (eg at 70 ° C the information is kept for 2,000 hours). The CD should be stored at a temperature of 25 ° C, which guarantees more than 1,000,000 hours.

The recommended minimum duration for sleep studies to be reliably evaluated is 6 hours.

The CD should be cleaned gently with a cloth moistened with mild (hand) soapy water and wiped dry, avoiding scratches on the CD. Keep the CD into its package when not in use.

None of the results provided by the Automatic Analyses contained in the BitmedLab software product line should be used as the sole criterion for medical diagnosis or patient treatment. This information should not be considered complete, nor is it to be trusted for the prescription of individual treatment. The user must understand that the results of the Automatic Analyses generated by the BitmedLab software product line are not exhaustive and must always be supervised and verified by medical personnel with adequate training.

In no case shall Sibel S.A. be responsible for any losses, damages or expenses derived from incorrect use of the device, the software or the computer devices (operating systems); or for flaws or accidents in other computer equipment.

1.5 PRODUCT DISPOSAL

The device support media is a CD. The CD and the packaging can be disposed in the household trash but it is recommended to recycle the packaging. No special consideration has to be taken when processing the CD media and packaging. Note: Korrvu® packaging can be recycled with the film left in place.

2. INSTALLING THE SOFTWARE

2.1 REQUIREMENTS

	Required	Recommended
Operating system	MS Windows XP, Vista, 7 or 8	
Processor	Intel Pentium 4, AMD Athlon	Double core processor
Memory	1024Mb	2048Mb
Free space in hard disk	100Mb	Several gigabytes to acquire synchronized digital video
USB Ports 1.1	Screen&Go/Sleep&Go: 2 (if a Bluetooth module and card reader are used) eXea: 1	
Screen resolution	1024 x 768	1280 x 1024 or higher
Capture of synchronized digital video	Free PCI Xpress slot (PCs) Free Xpress Card slot (Laptops)	

2.2 INSTALLING BITMEDLAB

We recommend closing all the applications running in the system before starting the installation. This reduces the possibility of conflicts between software affecting the installation.

Take the following steps to install the BitmedLab software product

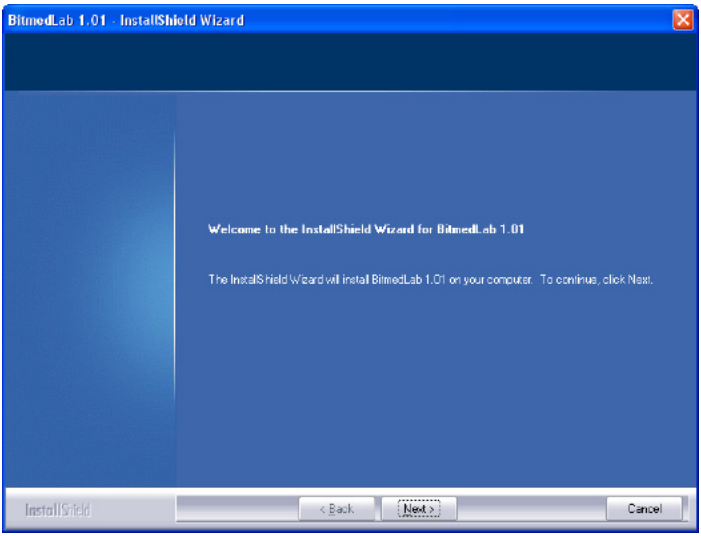
line:

Make sure the system has the necessary administration rights to install the drivers and applications.

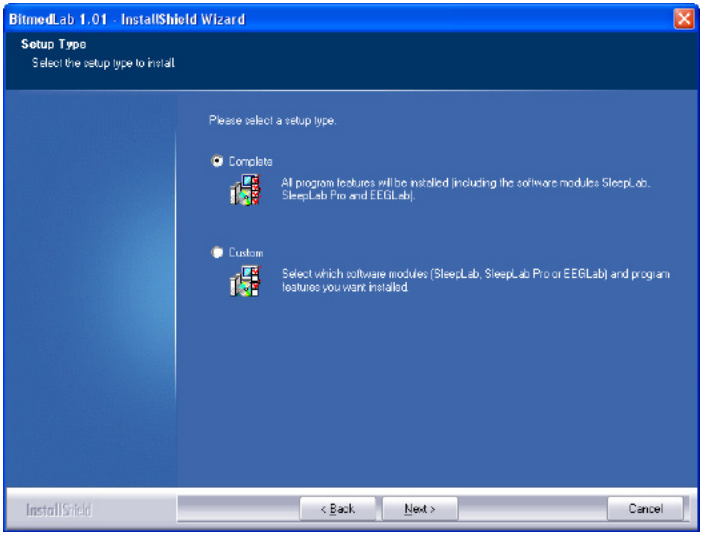
Click on Run in the Start menu of the Windows task bar. The Run dialog box will appear.

Write X:\setup.exe in the text box and click on Accept. X is the DVD/CD-ROM unit or access path to the folder containing the installation file. Click on Browse to locate the correct files in the hard disk or in the DVD/CD-ROM.

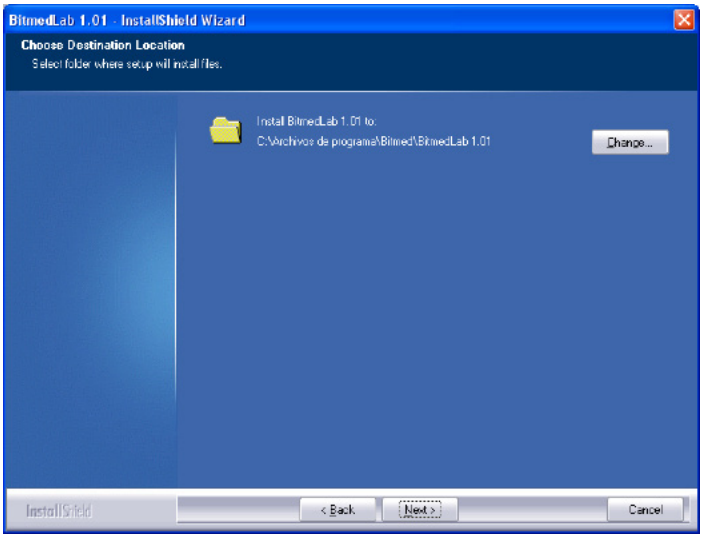
The installation program will immediately show the first panel of the installation wizard. Click on Next> to continue.


BitmedLab 1.01 - InstallShield Wizard
Welcome to the InstallShield Wizard for BitmedLab 1.01
The InstallShield Wizard will install BitmedLab 1.01 on your computer. To continue, click Next.
InstallShield
< Back
Next >
Cancel

The installation program can perform a complete program installation or customize the elements of the program to be installed. Choose the option you prefer and click on Next>.

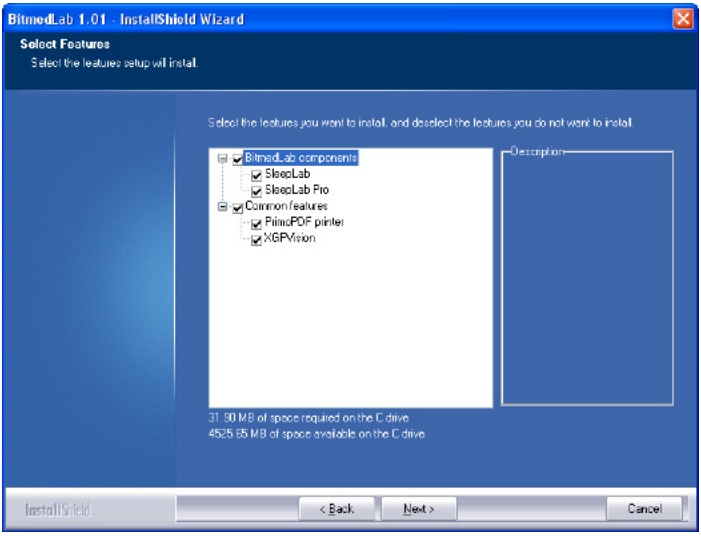

BitmedLab 1.01 - InstallShield Wizard
Setup Type
Select the setup type to install.
Please select a setup type.
Complete
All program features will be installed (including the software modules SleepLab, SleepLab Pro and EEGLab).
Custom
Select which software modules (SleepLab, SleepLab Pro or EEGLab) and program features you want installed.
InstallShield
< Back
Next >
Cancel

The next panel of the wizard lets you change the folder where the program files will be copied. If you want to change the default folder, click on Change. When you are finished, click on Next>.



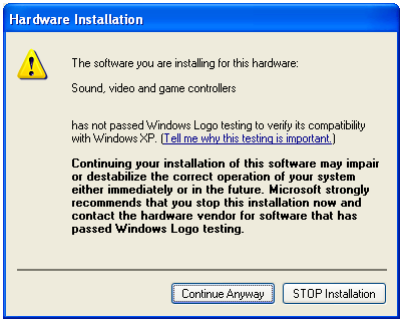
On the next screen, choose the elements that you want to install.

In BitmedLab Elements, choose the modules that you want to install: SleepLab and SleepLab Pro. The functionalities of each of these modules is described in Section 1.1. The PDF printer allows you to print the reports generated by the program in PDF format, while the XGPVIsion module allows you to acquire synchronized video, assuming you have obtained the corresponding license. Click on Next.


BitmedLab 1.01 - InstallShield Wizard
Select Features
Select the features setup will install.
Select the features you want to install, and deselect the features you do not want to install.
BitmedLab components
SleepLab
SleepLab Pro
Common features
PrimoPDF printer
XGPVision
Description
31.90 MB of space required on the C drive
4525.85 MB of space available on the C drive
InstallShield
< Back
Next >
Cancel

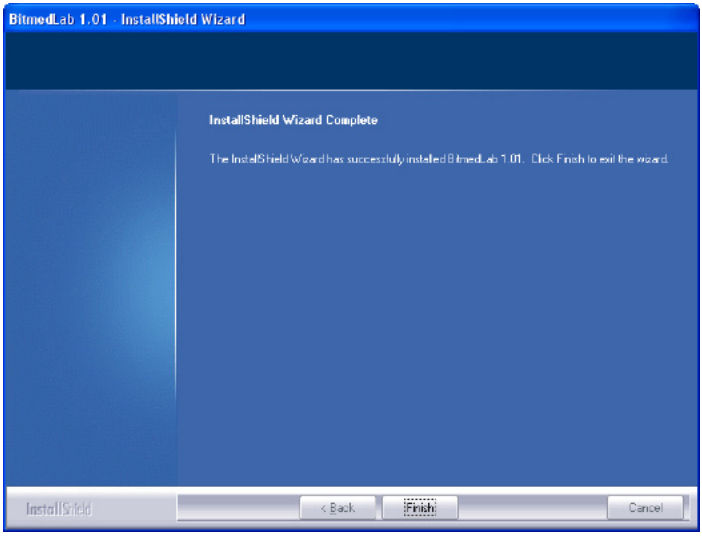
The installation program will copy the selected files. If you chose to install the PDF printer, the PrimoPDF installation program will start up automatically. Click on the Next button of all the screens until the installation of PrimoPDF has been completed.

If you chose the install XGPVision, a window will appear indicating that the software is installing hardware that has not passed the Windows logo test. Click on Continue.


Hardware Installation
The software you are installing for this hardware:
Sound, video and game controllers
has not passed Windows Logo testing to verify its compatibility with Windows XP. (Tell me why this testing is important.)
Continuing your installation of this software may impair or destabilize the correct operation of your system either immediately or in the future. Microsoft strongly recommends that you stop this installation now and contact the hardware vendor for software that has passed Windows Logo testing.
Continue Anyway
STOP Installation

If a message appears requesting confirmation to overwrite files, click on "No to all".

When the installation is complete, click on Finish. The BitmedLab software line of products is ready for use.



2.3 INSTALLING THE USB DRIVER (EXEA SYSTEMS)

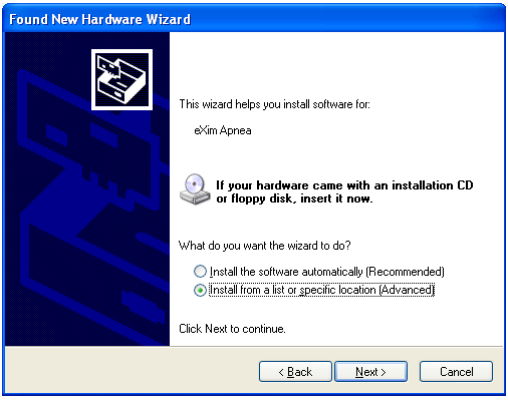
The first time the Bitmed eXea system is connected to the PC, Windows detects the new device and requests the necessary files to install the driver.

2.3.1 WINDOWS XP

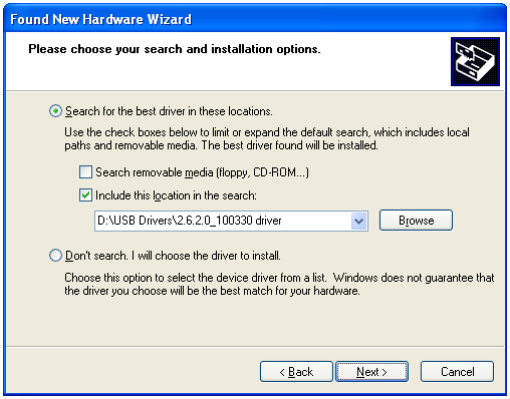
Connect the eXea system to a free USB port in the PC. The New hardware found wizard will start up immediately. Choose "Not at this time" and click on the Next button.

Found New Hardware Wizard
Welcome to the Found New Hardware Wizard
Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission).
Read our privacy policy
Can Windows connect to Windows Update to search for software?
Yes, this time only
Yes, now and every time I connect a device
No, not this time
Click Next to continue.
< Back
Next >
Cancel

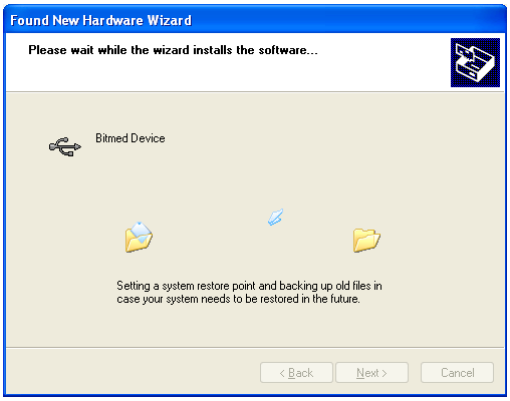
In the next screen, choose the option Install from a list or specific location (advanced) and click on Next.


Found New Hardware Wizard
This wizard helps you install software for:
eXim Apnea
If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel

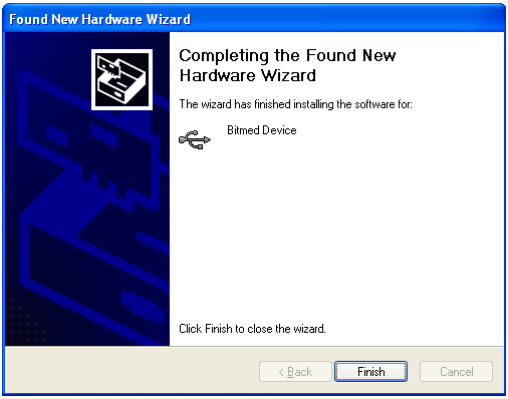
In the following window, select "Search for the best driver in these locations" and "Include this location in the search". Choose the USB Drivers folder in the BitmedLab CD and click again on Next.


Found New Hardware Wizard
Please choose your search and installation options.
Search for the best driver in these locations.
Use the check boxes below to limit or expand the default search, which includes local paths and removable media. The best driver found will be installed.
Search removable media (floppy, CD-ROM...)
Include this location in the search:
D:\USB Drivers\2.6.2.0_100330 driver
Browse
Don't search. I will choose the driver to install.
Choose this option to select the device driver from a list. Windows does not guarantee that the driver you choose will be the best match for your hardware.
< Back
Next >
Cancel

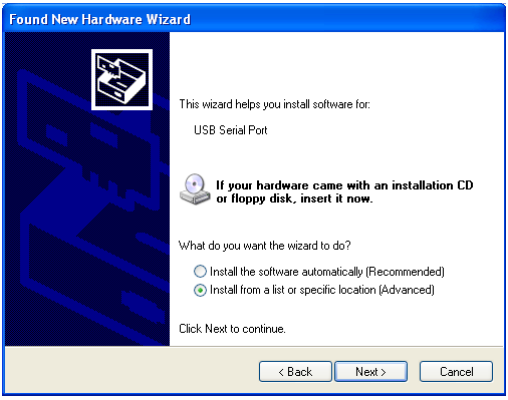
Windows will start installing the driver. Click on Next in the window that appears.


Found New Hardware Wizard
Please wait while the wizard installs the software...
Bitmed Device
Setting a system restore point and backing up old files in case your system needs to be restored in the future.
< Back
Next >
Cancel

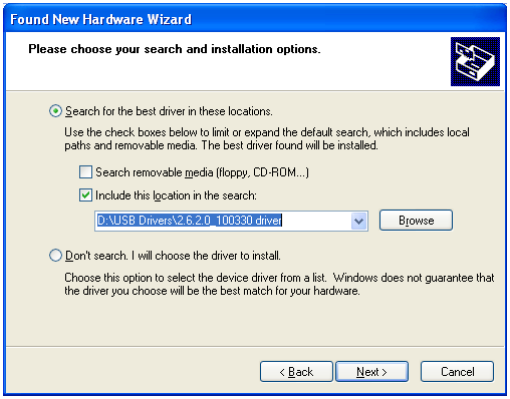
Once the driver installation is completed, click on Close.



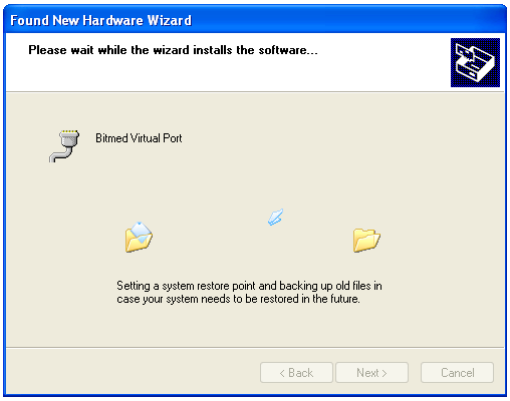
The system will then detect a new device called Bitmed Virtual Port. Choose the Install option from a list or specific location and click on Next.


Found New Hardware Wizard
This wizard helps you install software for:
USB Serial Port
If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel

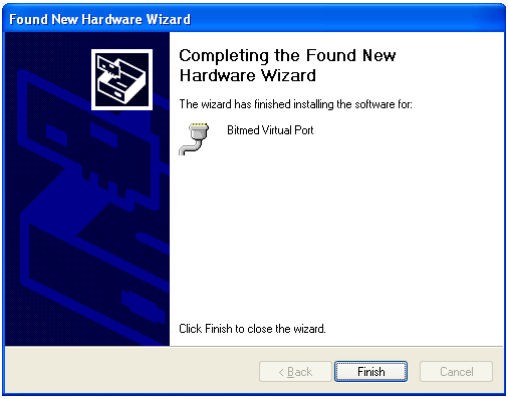
In the following window, select "Search for the best driver in these locations" and "Include this location in the search". Choose the USB Drivers folder in the BitmedLab CD and click again on Next.


Found New Hardware Wizard
Please choose your search and installation options.
Search for the best driver in these locations.
Use the check boxes below to limit or expand the default search, which includes local paths and removable media. The best driver found will be installed.
Search removable media (floppy, CD-ROM...)
Include this location in the search:
D:\USB Drivers\2.6.2.0_100330 driver
Browse
Don't search. I will choose the driver to install.
Choose this option to select the device driver from a list. Windows does not guarantee that the driver you choose will be the best match for your hardware.
< Back
Next >
Cancel

Windows will start installing the driver. Click on Next in the window that appears.


Found New Hardware Wizard
Please wait while the wizard installs the software...
Bitmed Virtual Port
Setting a system restore point and backing up old files in case your system needs to be restored in the future.
< Back
Next >
Cancel

Once the driver installation is completed, click on Close.



Then access the Windows Control Panel from the Start menu > Control panel. Access the Performance and maintenance > System option.

Click on the Device manager button in the Hardware tab.

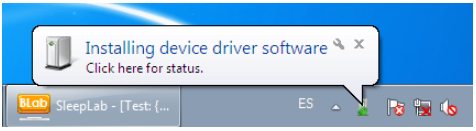
Open the Universal serial bus (USB) drivers option and double click on Bitmed device.

The Bitmed device Properties window will open. Choose the Advanced tab and disable the Load VCP option. If the Load VCP option does not appear, restart the PC and repeat this step.

Click on Accept and close all the windows that have been left open. Disconnect the Bitmed eXea from the USB port and connect it again.

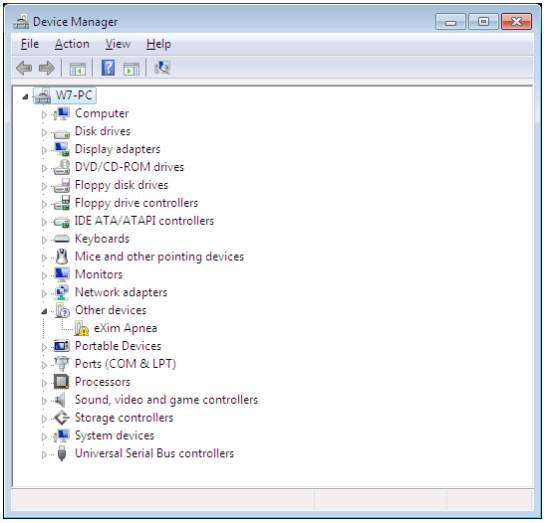
2.3.2 WINDOWS VISTA, WINDOWS 7 AND WINDOWS 8

Connect the eXea system to a free USB port in the PC. Windows will attempt to install the device automatically.

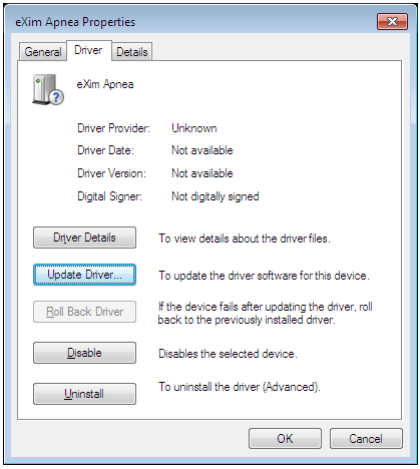


However, Windows will not install the device driver automatically. Open the device manager via Start > Control panel > Hardware

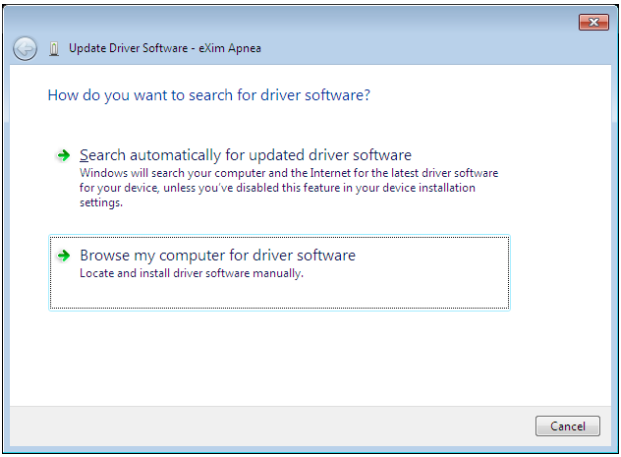
and sound > Device manager. In Device manager, locate the entry that corresponds to your device and double click on it.



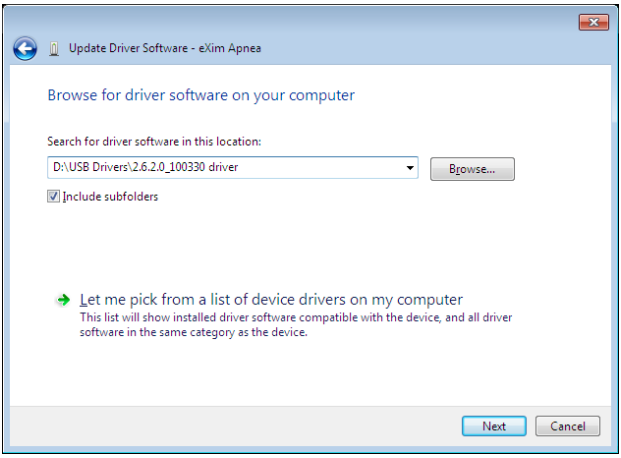
Choose the Driver tab and click on the Update driver button.



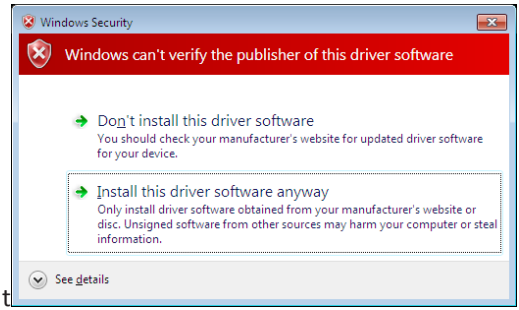
Click on "Search for driver software on your computer".


Update Driver Software - eXim Apnea
How do you want to search for driver software?
Search automatically for updated driver software
Windows will search your computer and the Internet for the latest driver software for your device, unless you've disabled this feature in your device installation settings.
Browse my computer for driver software
Locate and install driver software manually.
Cancel

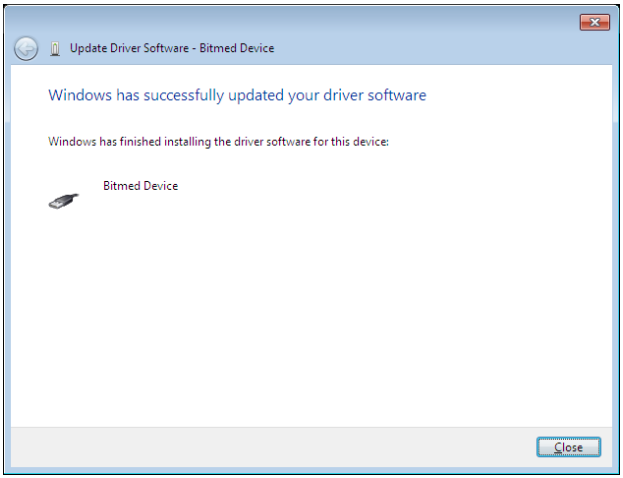
Use the Browse option to find the USB Drivers folder in the BitmedLab software CD. Click on Next.


Update Driver Software - eXim Apnea
Browse for driver software on your computer
Search for driver software in this location:
D:\USB Drivers\2.6.2.0_100330 driver
Browse...
Include subfolders
Let me pick from a list of device drivers on my computer
This list will show installed driver software compatible with the device, and all driver software in the same category as the device.
Next
Cancel

Windows will show a message indicating that the manufacturer of the driver software could not be verified. Click on "Install this driver software anyway".


Windows Security
Windows can't verify the publisher of this driver software
Don't install this driver software
You should check your manufacturer's website for updated driver software for your device.
Install this driver software anyway
Only install driver software obtained from your manufacturer's website or disc. Unsigned software from other sources may harm your computer or steal information.
See details

Once the device driver installation is completed, click on Close.


Update Driver Software - Bitmed Device
Windows has successfully updated your driver software
Windows has finished installing the driver software for this device:
Bitmed Device
Close

Windows will detect another new device, but will not automatically install the driver of the device. Open the device manager via the Start menu > Control panel > Hardware and sound > Device manager. In Device manager, locate the Bitmed virtual port entry and double click on it.

Choose the Driver tab and click on the Update driver button.

Click on "Search for driver software on your computer".

Use the Browse option to find the USB Drivers folder in the BitmedLab software CD. Click on Next.

Windows will show a message indicating that the publisher of the driver software could not be verified. Click on "Install this driver software anyway".

Once the device driver installation is completed, click on Close.

In Device manager, open the Universal serial bus (USB) drivers option and double click on Bitmed device.

The Bitmed device Properties window will open. Choose the Advanced tab and disable the Load VCP option. If the Load VCP option does not appear, restart the PC and repeat this step.

Click on Accept and close all the windows that have been left open. Disconnect the Bitmed eXea from the USB port and connect it again.

2.4 INSTALLING THE BLUETOOTH MODULE (SLEEP&GO SYSTEMS)

If you have purchased a Bluetooth module with your Bitmed Sleep&Go system, follow the instructions in the manual of the module to install the module driver.

3. USING THE PROGAM WITH THE SCREEN&GO AND SLEEP&GO SYSTEMS

3.1 FIRST STEPS

3.1.1 STARTING UP THE SLEEPLAB MODULE

There are two ways to start the SleepLab module:

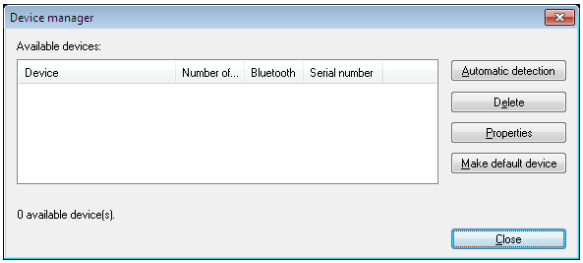
Click on the SleepLab icon in the Windows Desktop.

In the Windows Start menu, click All the programs, go to the BitmedLab folder and click on the SleepLab icon.

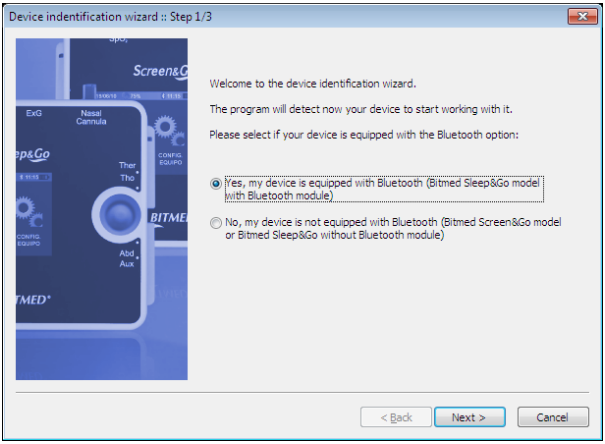
3.1.2 REGISTERING THE SCREEN&GO/SLEEP&GO IN THE SOFTWARE

Before starting to use your Screen&Go/Sleep&Go system, you must register it in the SleepLab software. This procedure is required only once and ensures that your program recognizes the characteristics of your computer and those of the optional modules you have purchased.

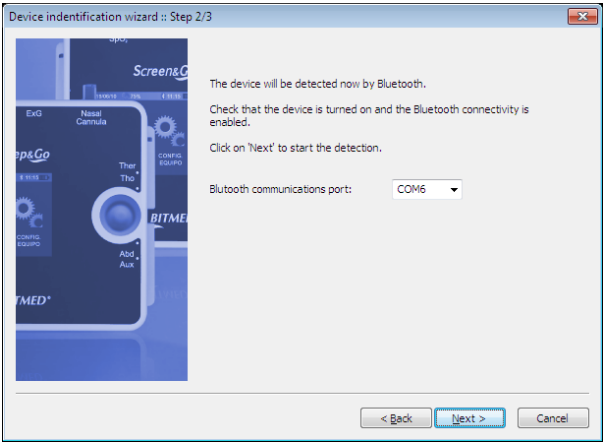
Go to the Polygraph menu > Device manager.

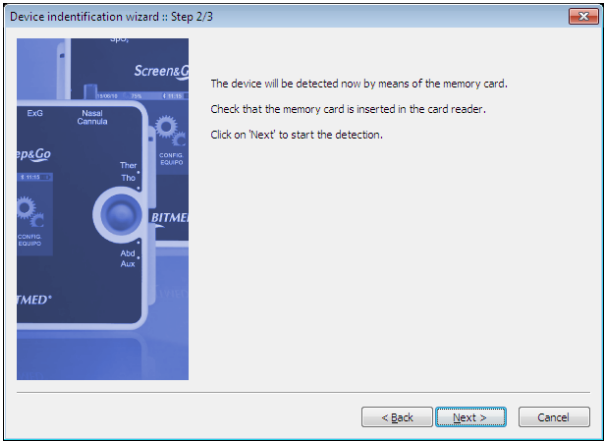


Click on Automatic detection. The Device identification wizard will start up. If you have a Sleep&Go system with a Bluetooth module, mark the option "Yes, my device has Bluetooth communication". If not, select the option "No, my device does not have Bluetooth communication". Click on Next.

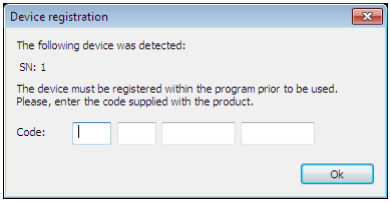

Device indentification wizard :: Step 1/3
Welcome to the device identification wizard.
The program will detect now your device to start working with it.
Please select if your device is equipped with the Bluetooth option:
Yes, my device is equipped with Bluetooth (Bitmed Sleep&Go model with Bluetooth module)
No, my device is not equipped with Bluetooth (Bitmed Screen&Go model or Bitmed Sleep&Go without Bluetooth module)
< Back
Next >
Cancel

If you have a Sleep&Go system with a Bluetooth module, make sure that the Bluetooth module is running and select the Bluetooth communications port that the device is connected to (you can find this in the Windows Control panel). If not, remove the memory card from the device and insert it in the PC card reader (remember to switch off the device before removing the memory card). Click on Next.

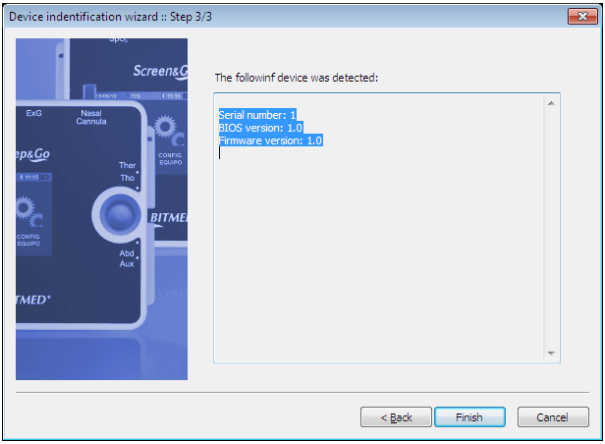

Device indentification wizard :: Step 2/3
The device will be detected now by Bluetooth.
Check that the device is turned on and the Bluetooth connectivity is enabled.
Click on 'Next' to start the detection.
Blutooth communications port:
COM6
< Back
Next >
Cancel


Device indentification wizard :: Step 2/3
The device will be detected now by means of the memory card.
Check that the memory card is inserted in the card reader.
Click on 'Next' to start the detection.
< Back
Next >
Cancel

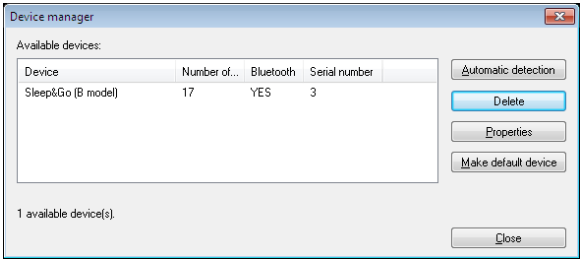
A window will open to enter the password provided with your copy of the BitmedLab software product line. Enter the password and click on Accept.


Device registration
The following device was detected:
SN: 1
The device must be registered within the program prior to be used.
Please, enter the code supplied with the product.
Code:
Ok

The wizard will detect Screen&Go/Sleep&Go and present the compiled information. Click on Finish.



Note that the device has been registered in the software. The device is now ready to be used.

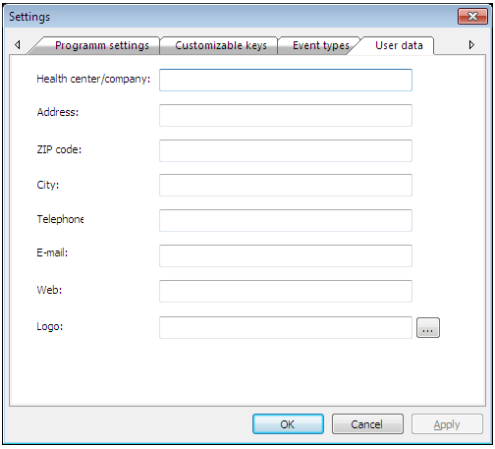


3.1.3 ENTERING USER DATA

BitmedLab lets you enter user data and an image with your logo. These will appear in the header of printed documents and in the report generated for each test.

Click on Configuration in the Tools menu.

Open the User data tab and fill in the fields with the user data.



To select a logo, click on the "…" button of the Logotype field and choose your logo image. The image must be stored in a file with BMP format.

3.1.4 ENTERING THE SLEEP&GO DATE AND TIME

Before starting tests with your Sleep&Go system, we recommend entering the date and time of the device. This information is used when programming tests to be performed in holter mode, in which the device starts monitoring the patient on a specific date, at a specific time.

The device date and time option can only be entered from BitmedLab software in Sleep&Go systems equipped with the Bluetooth communication module. In all the other systems, the date and time must be entered by using the graphics screen of the device. Refer to the device manual.

Go to the Polygraph menu > Enter date/time.

If more than one Screen&Go/Sleep&Go is available, choose one.

A window appears with the date and time of the PC. Modify the date and time, if necessary. When you are ready, click on Enter to apply the changes to your Sleep&Go.

3.1.5 DELETING STUDIES FROM THE SLEEP&GO MEMORY CARD

Each time you perform a test, whether in holter or real-time mode, a file is generated in the Screen&Go/Sleep&Go memory card. This file stores all the biomedical data compiled by the device. When the test is transferred to the PC, these files are automatically deleted. However, you may want to delete the files from the memory card. To do so, insert the card in the card reader of your PC and delete the files with .DAT extension from Windows explorer. Be sure to switch off Screen&Go/Sleep&Go before removing the memory card. You can also delete all the test files using the BitmedLab software:

Click on the Delete memory option of the Polygraph menu.

Confirm deletion of all the tests stored in your Sleep&Go memory card.

The memory card test deletion option is only available from BitmedLab software in Sleep&Go systems equipped with the Bluetooth communication module.

	Before deleting the contents of the memory card, make sure that all test that you are interested in keeping have been downloaded to the PC. The deletion procedure will eliminate all the tests stored in the memory card. The user will not be able to choose which tests to delete and which tests not to delete.

3.2 HOME SCREEN OF THE PROGRAM: THE SLEEPLAB MODULE WORKFLOW CHART

The BitmedLab software home screen has been designed to facilitate the workflow of the Sleep Disorders Unit as much as possible. Only the most common tasks are shown and these can be accessed by the following buttons:

Device configurations: this opens a wizard that allows the user to manage the device configurations used to perform the polygraph

or screening studies (See Section 3.3).

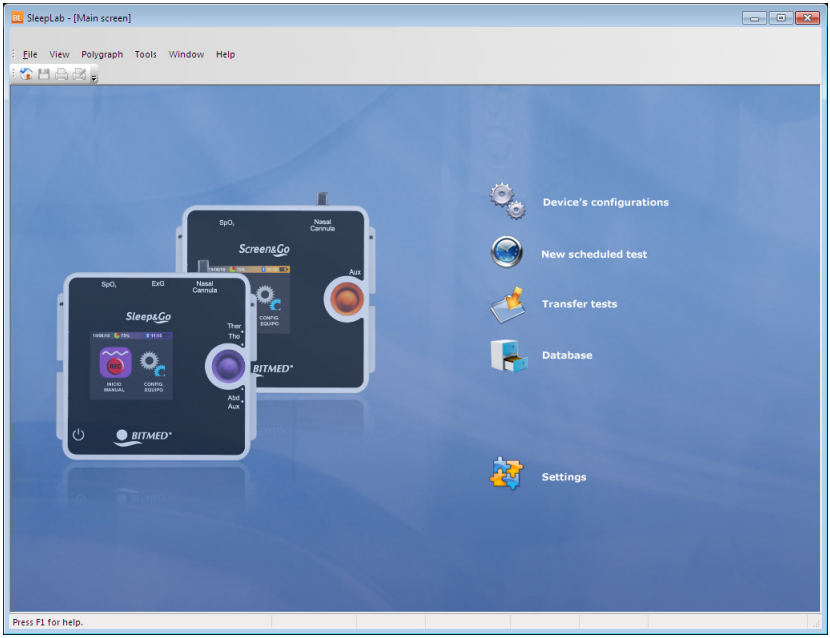
New scheduled test: this opens a wizard that allows the user to program a test for a specific date and time (See Section 3.4).

Download tests: this opens a wizard that allows the user to download tests from the Screen&Go/Sleep&Go system to the PC. It also allows subsequent review of tests (See Section 3.5).

Database: open the patients and tests database. Patients and their tests can be managed from the database (new patients, discontinued patients, test reviews, consultation of work pending, etc.) (See Section 3.6).

Settings: this accesses the general options of the program (user data, type of events, custom keys, general options, etc.).

The home screen can be accessed at any time by clicking on the icon of the toolbar.



3.3 TEST SETTINGS

Each polygraphy or screening test of the OSAS can be configured previously so the device recognizes which channels (sensors) are going to be acquired and the sampling frequencies that are going to be used. All these parameters are grouped in an "channel configuration". Each channel configuration has a name assigned by the user so it is easy to recognize.

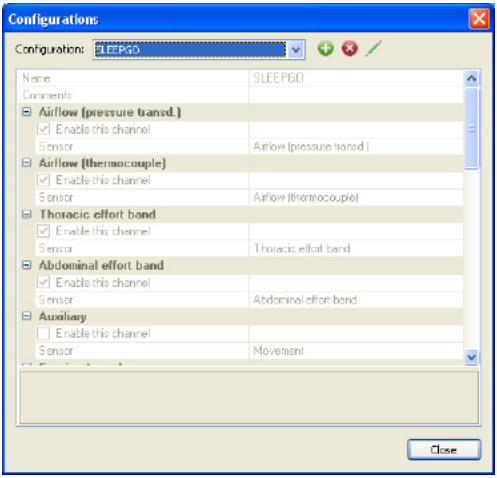
During the performance of the test, check that the sensor connected to each channel corresponds to the selected channel configuration.

The configurations are stored in the device memory card, and a maximum of ten is allowed at the same time. The extension of the configuration files is .CFG. The SleepLab software module can generate, manage and store as many configurations as necessary.

Your device also has a default channelevice configuration that is used when the test is started manually from the device itself. This configuration is labeled as "Internal" in the device. If you have a Sleep&Go with a Bluetooth communication module, the device default configuration can be set from the BitmedLab software. If not, this option will be disabled and must be done from the device itself (refer to the User's Manual of the device), by choosing from the configurations found in the memory card. Any of these configurations can be set as "Internal" from the device itself.

3.3.1 CREATING, MODIFYING AND DELETING CONFIGURATIONS

In the main menu go to Polygraph > Configurations.



The following configurations are supplied by default with the software:

- CSCR: Screen&Go basic model.
- CSCRSPO: Screen&Go model with pulseoximetry option.
- CSLPA: Sleep&Go A model.
- CSLPB: Sleep&Go B model.
- CSLPBEXG: Sleep&Go B model with ExG module.

In the Configurations window, click the button to add a new configuration. Then select the polygraph model for which the configuration will be created. Editing of channels to be acquired during the test will be enabled. Select the ones to use and configure the sensors that will be connected to each of them. You can also change the sampling rate of some of them. However, others have a fixed sampling rate and can not be changed. Do not forget to enter up to 8 characters in the Name field. When finished, click the button to save the changes or the button to discard them.

Use the button to delete the configuration selected in the Configurations list.

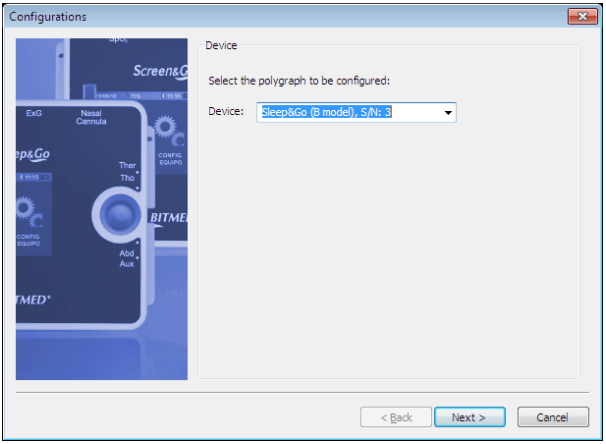
Finally, the button allows you to modify the configuration selected in the Configurations list. Again, use the buttons and to confirm or discard the changes.

The following characters are available for the configuration name: letters from A to Z and numbers from 0 to 9.

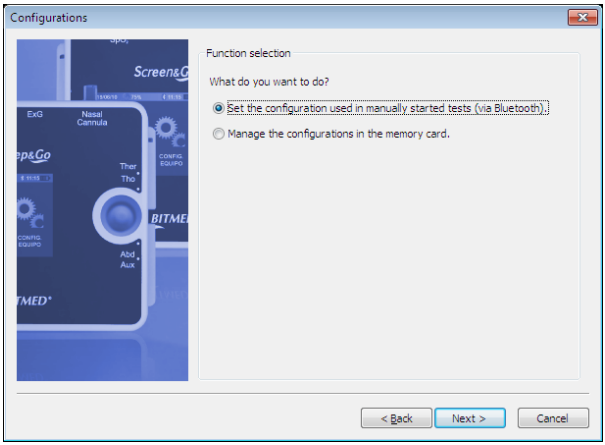
3.3.2 SETTING THE DEVICE DEFAULT CONFIGURATION USING BLUETOOTH (ONLY SLEEP&GO)

Click on Device configurations in the home screen.

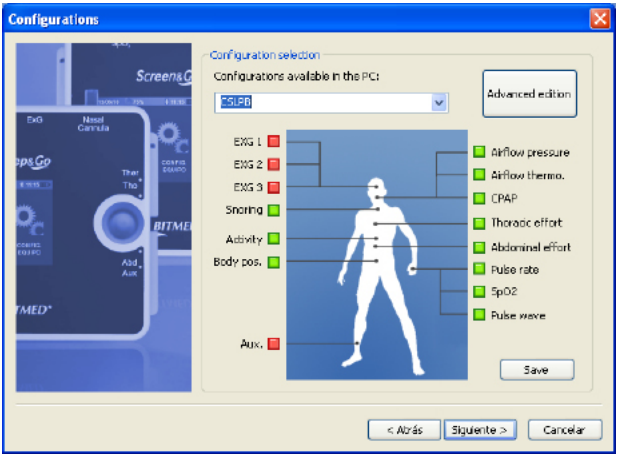
Each device configuration is associated with a Sleep&Go system by means of a specific serial number. The first step in the wizard is to choose the device that you want to establish the configurations for. Click on Next.



In the next screen, choose Set the manual start configuration (via Bluetooth) and click on Next.

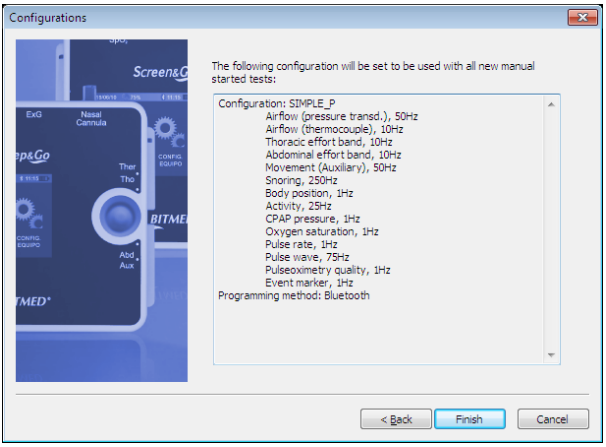

Configurations
Function selection
What do you want to do?
Set the configuration used in manually started tests (via Bluetooth).
Manage the configurations in the memory card.
< Back
Next >
Cancel

Choose one of the configurations in the list. You can modify a configuration in the list or create a new one by clicking on the "Edit PC configurations" button. The graph shows the channels that will be acquired (green) or not (red), depending on the setting chosen. You can also edit a configuration in situ, activating or deactivating channels by clicking the appropriate button. If you also want to save the changes as a new configuration click the Save button and the program will ask for a name for the configuration. Click on Next.



Finally, a summary of the default configuration for the device will

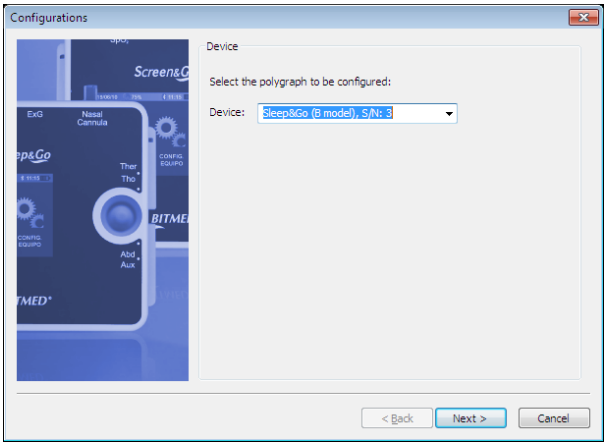
be shown. Make sure that Bluetooth communication is enabled in your device and click on Finish.



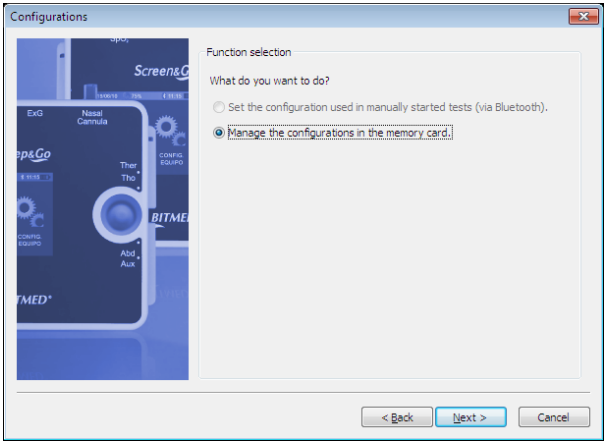
3.3.3 MANAGING THE DEVICE CONFIGURATIONS IN THE MEMORY CARD

Click on Device configurations in the home screen.

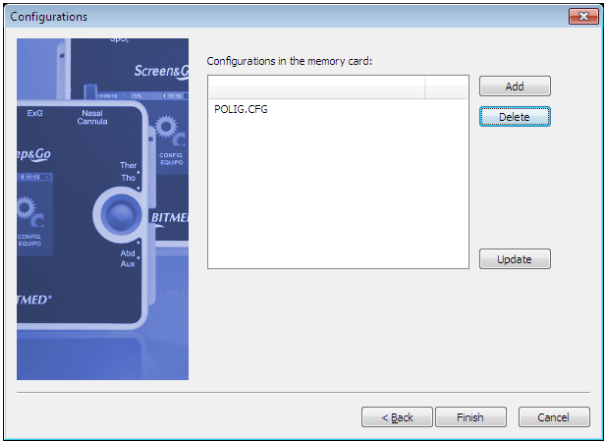
Each device test setting is associated with a Sleep&Go system by means of a specific serial number. The first step in the wizard is to choose the device that you want to establish the configurations for. Click on Next.



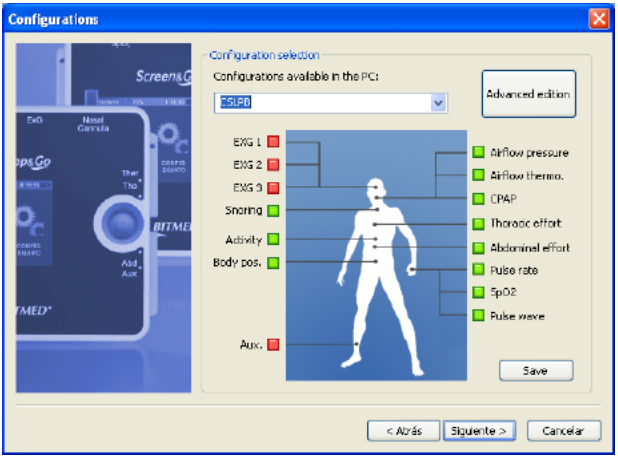
In the following screen, choose "Manage memory card configurations". Make sure you have inserted the memory card in the PC card reader and click on Next.


Configurations
Function selection
What do you want to do?
Set the configuration used in manually started tests (via Bluetooth).
Manage the configurations in the memory card.
< Back
Next >
Cancel

The following window shows a list of device configurations in the memory card. Remember that there can be no more than ten configurations in the memory card at the same time. Any of these configurations can be deleted by clicking on the Delete button.



Any of the configurations defined in BitmedLab can also be added by clicking on the Add button. In the new window, choose one of the configurations in the list. You can modify a setting in the list or create a new one by clicking on the "Edit PC configurations" button. The graph shows the channels that will be acquired (green) or not (red), depending on the setting chosen. You can also edit a configuration in situ, activating or deactivating channels by clicking the appropriate button. If you also want to save the changes as a new configuration click the Save button and the program will ask for a name for the configuration. Click on Next.



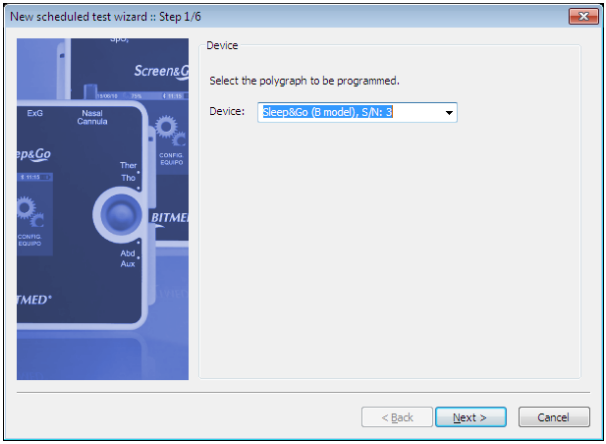
Click on Finish when you are finished.

3.4 PROGRAMMING AN AUTOMATIC TEST

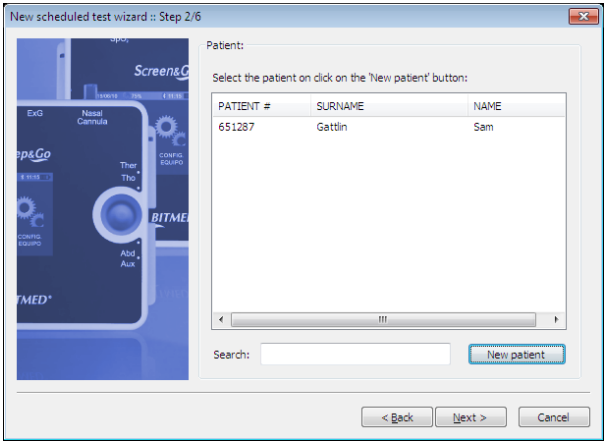
Take the following steps to set up your Screen&Go/Sleep&Go in order to start an automatic test in holter mode at a specific date and time:

Click on "New programmed test" in the home screen.

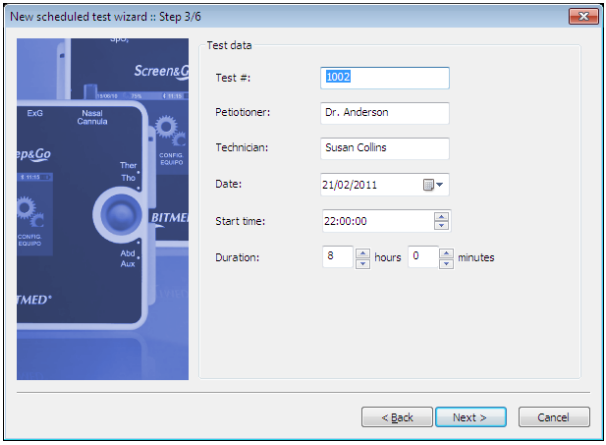
The wizard for the new programmed test will start up. Choose the device that you wish to program.



Choose the patient associated with the test. You can search for the patient by entering any of the patient's data in the Filter field. If the patient is not in the database, you can add the patient at this time by clicking on New patient. Once the patient has been selected, click on Next.

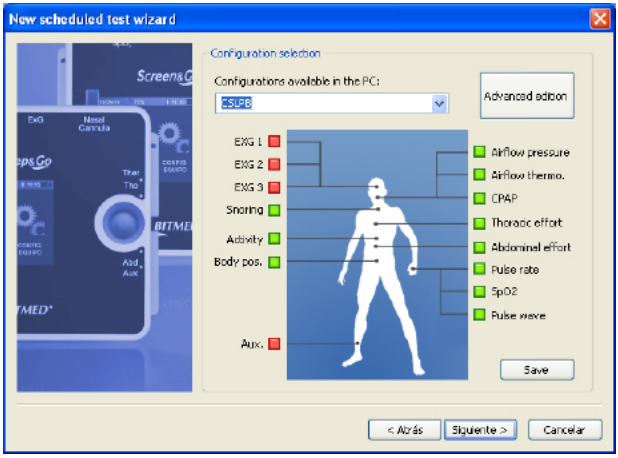


Then enter the test data, including the start date and time of the study and its duration. The device will complete the test automatically. Click on Next.



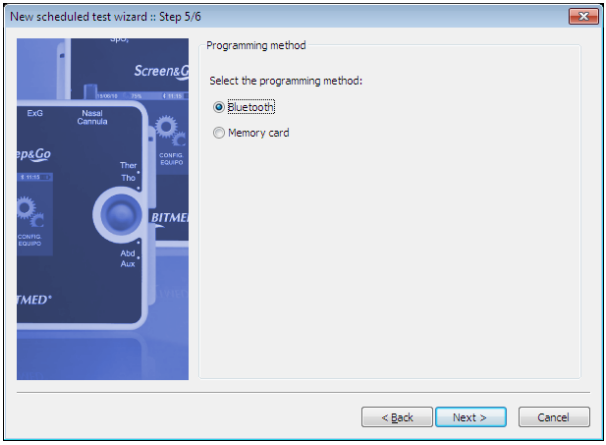
Choose the type of test to be performed. You can modify one of the available device configurations or create a new one by clicking on the "Edit PC configurations" button. The graph shows the channels that will be acquired (green) or not (red), depending on the setting chosen. You can also edit a configuration in situ, activating or deactivating channels by clicking the appropriate button. If you also want to save the changes as a new configuration click the Save button and the program will ask for a name for the configuration.

Click on Next.

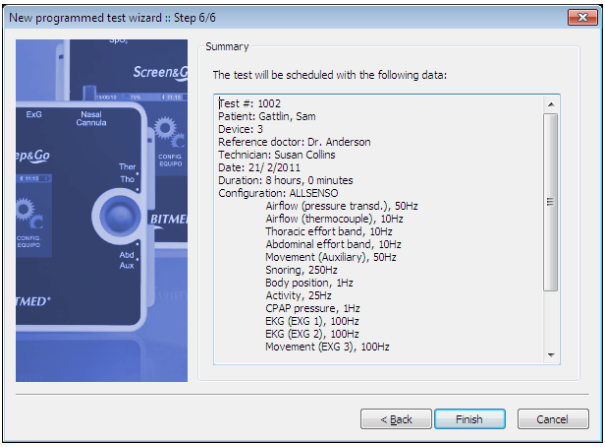


If you have a Sleep&Go system with a Bluetooth communication module, the test can be programmed directly via Bluetooth. Make sure that Sleep&Go is switched on, Bluetooth is enabled and choose option A via Bluetooth. Click on Next.

If not, remove the device memory card (remember to switch off the device before removing the memory card), insert it into the PC card reader and choose option A via the memory card. Click on Next.



Finally, a summary of the automatic test to be performed is shown. Click on Finish.



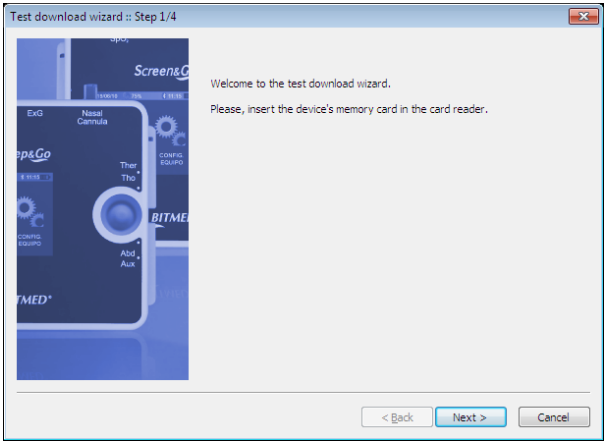
If the test was programmed via the memory card, wait until the program delivers a message indicating that programming has been completed successfully. Remove the card from the card reader and place it n the device again. Switch on the device and wait until the main screen appears (the one with the manual start option). The device will detect a new test and is now ready for use. Now you can switch off the device.

3.5 DOWNLOADING THE COMPLETED TEST

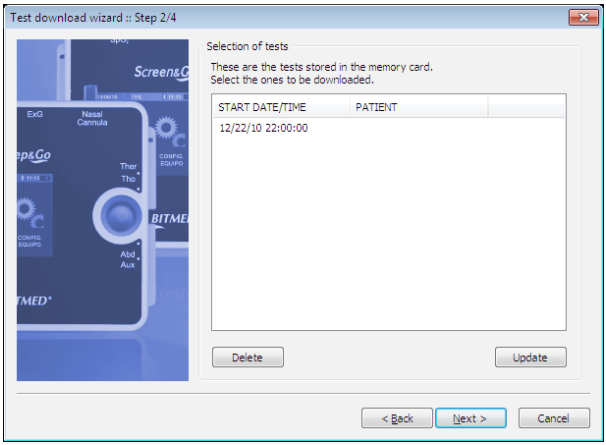
Once a test has been obtained in holter mode (whether started automatically or manually) it is necessary to download the test to the PC for review and to generate a report.

To do so, remove the memory card from the Screen&Go/Sleep&Go system and insert it into the PC card reader (remember to switch off the device before removing the memory card). The take the following steps in the BitmedLab software:

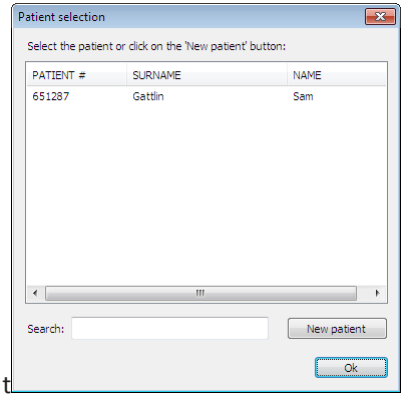
Click on "Download tests" in the home screen. The download test wizard will start up. Click on Next.


Test download wizard :: Step 1/4
Welcome to the test download wizard.
Please, insert the device's memory card in the card reader.
< Back
Next >
Cancel

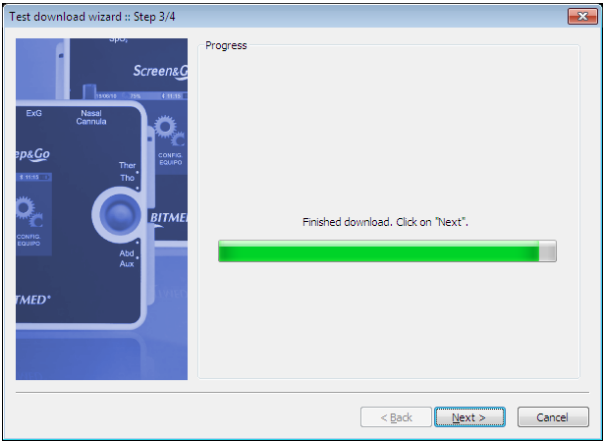
The program will list the tests available in the memory card. Choose the test you wish to download and click on Next. If you wish to delete any of the tests from the card without downloading them to the computer, choose the test and click on Delete. The test chosen for downloading will be automatically deleted from the memory card when the process has concluded.



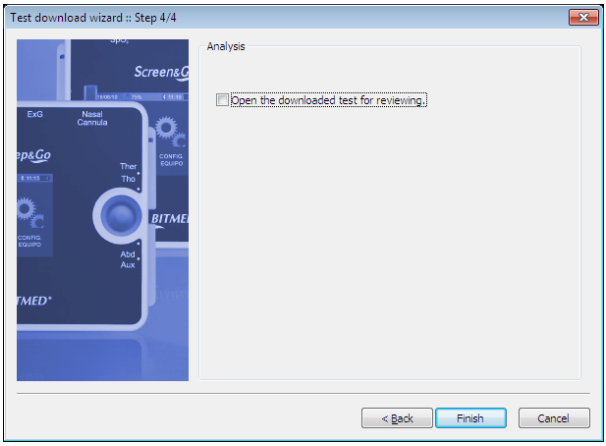
If the test was started automatically, the program will automatically associate the test with the patient selected during test programming. If the test was started manually, the patient associated with the test must be selected manually from all the patients in the database, or a new patient created.



The program will then download the test. Wait until the process has finished. When the message appears indicating that the transfer has been completed, click on Next.



Once the test has been downloaded, an option appears to open it immediately for review. In any event, the test can be opened afterwards at any time from the database window. Click on Finish.



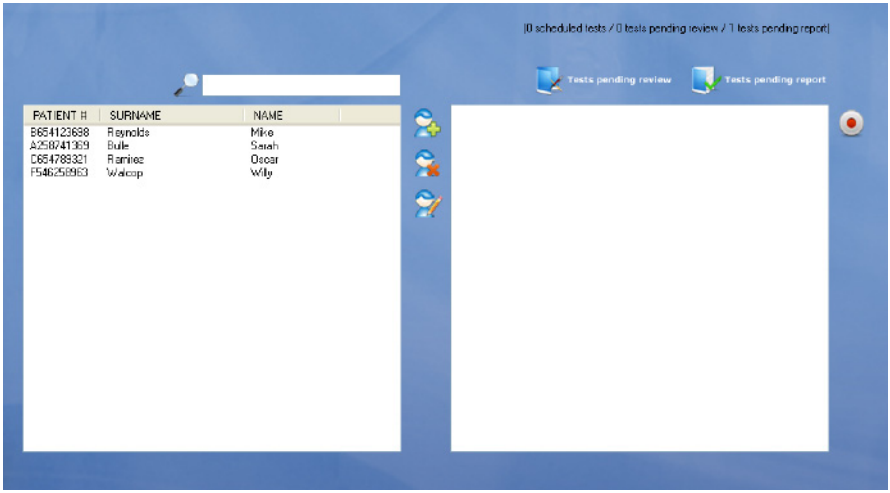
3.6 MANAGING PATIENTS AND TESTS: THE DATABASE

The BitmedLab database provides easy management of all your patients and tests. Access it by clicking on the Database button.

The database window is divided into two highly differentiated areas. On the left is the list of patients, showing the name, last name and number of the patient. The list can be ordered by any of these fields by clicking on the field header.

On the right of the patient list are the buttons used to add, modify or delete a patient.

The area on the right is used to display a tree with the tests and documents associated with the selected patient. The information is updated every time a different patient is selected. Each test includes the start date and time, duration and status of the test. You can also associate any type of file to the patient, under the Documents branch. More information on how to do this can be found below.

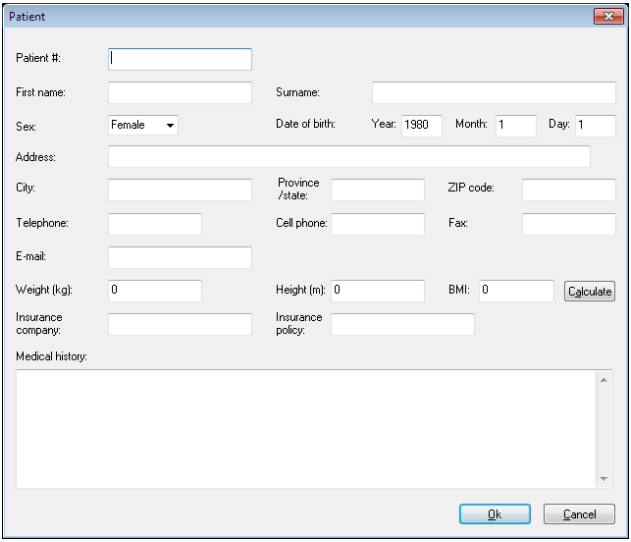


3.6.1 ADDING, MODIFYING AND DELETING PATIENTS

Adding a patient to the database

In the database window click on the New patient button .

Fill in the patient data in the Patient window and click on Ok.



Modifying patient data

In the database window select the patient to edit from the patient list and click on the Edit patient button .

Edit the patient data in the Patient edit window and click on Ok.

Deleting a patient from the database

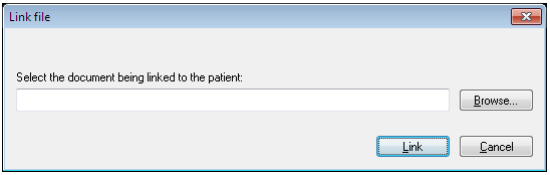
In the database window select the patient to delete from the patient list and click on the Delete patient button .

Confirm that you wish to delete the patient and the associated tests.

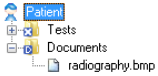
3.6.2 ASSOCIATING DOCUMENTS TO A PATIENT

Select the patient and right click on the Patient tree documents folder. Select the Associate document option.

Click on the Browse button in the Associate file window and choose the file that you wish to associate with the patient.



Click on Associate and confirm that the file has been associated with the patient. You can open or delete the association by clicking on the document icon.

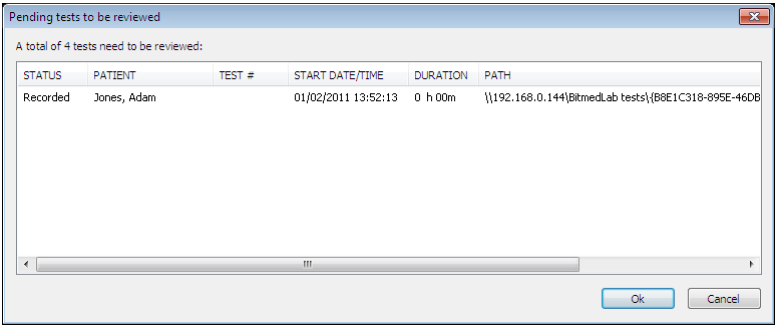


3.6.3 SEARCHING IN THE DATABASE

The Search text field can be used to filter the results shown, depending on the text that is entered. Filtering can be applied to multiple data, of both patients and tests (last name, name, patient number, insurance company, medical record, test number, doctor of reference, test date, etc.).

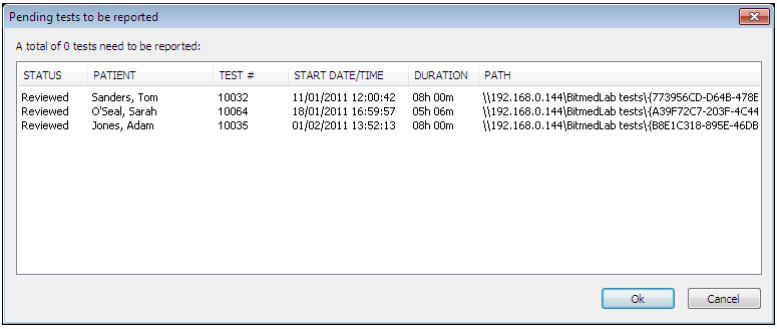
3.6.4 TESTS PENDING REVIEW OR REPORT

The Tests pending review button displays a window with the list of all the tests that have been downloaded to the PC and have yet to be reviewed.



On the other hand, the Tests pending reports button is similar to the one above, but in this case it lists the tests that have been

reviewed but for which a report has not yet been generated.



These two functionalities make it easier for the user to find work that is still pending completion. Double click on any of the tests to open them.

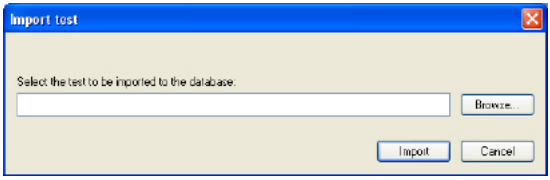
3.7 IMPORTING AND EXPORTING TESTS

Importing tests

Select the patient to whom you want to add the test and right click the mouse on the Tests folder of the tree.

In the context menu select Import test.

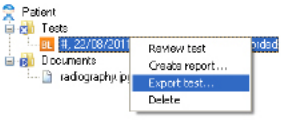
In the Import dialog box, select the test file to be added using the Browse button and click on Import. The test will be added to the patient.



Exporting tests

To export a test select it in the database and click the right mouse button.

Select Export test in the menu.



In the Save As dialog box select the name and path to the file where the file will be saved.

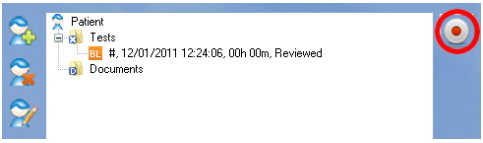
3.8 PERFORMING TESTS IN REAL TIME (ONLY SLEEP&GO)

You can perform, store and monitor tests in real time directly in the PC with all the Bitmed Sleep&Go systems including the Bluetooth module.

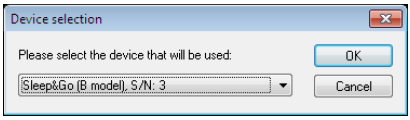
3.8.1 STARTING THE REAL-TIME TEST

Place all the sensors and electrodes required for the test on the patient, as described in the User's Manual of the device.

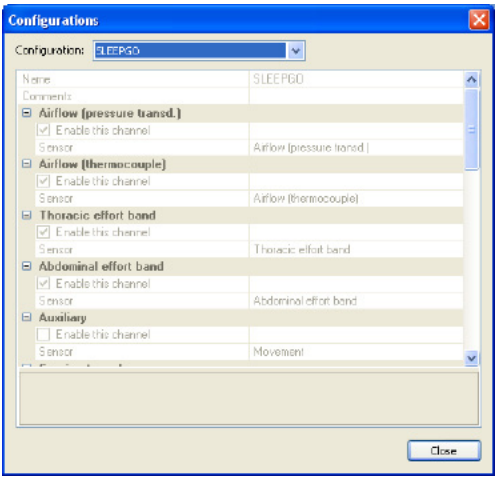
In the database window, choose the patient to whom the test will be associated and click on the Start a new real time test with the Sleep&Go button.



If more than on Sleep&Go is available, choose the one you wish to perform the test with.



The Configurations window will appear. Choose the device configuration that you wish to use.



The program will request the folder and name with which to store the test, offering a default name. Click on Save to start the test.

	Do not turn off the PC when performing a real-time test. Stop the real-time test first.

3.8.2 COMPLETING TEST ACQUISITION

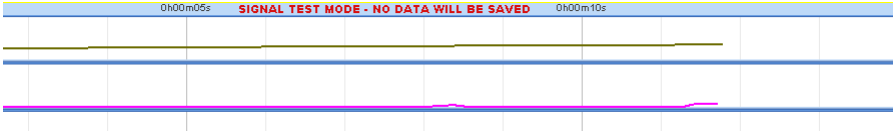
Click on the Finish test button ■. The test acquisition will stop after a few seconds and the device will stop recording data in the memory card.

3.8.3 SIGNAL TEST

Entering and exiting the signal test mode while the test is being performed

At any time during the performance of the test, the user can use the Signal test button ● on the Test toolbar to momentarily stop recording the data from Sleep&Go in the PC. However, the

biomedical signals will continue to be displayed on the screen. Use this option, for example, to relocate a sensor that has moved or been placed incorrectly and to check changes in the sensor signal, without any of it being stored in the test.



To continue the test from the point at which the signal test had begun, click again on the same button.

Start all the tests in signal test mode

For starting automatically all the new real-time recordings in the signal test mode, perform the following steps:

Go to the Tools menu > Options.

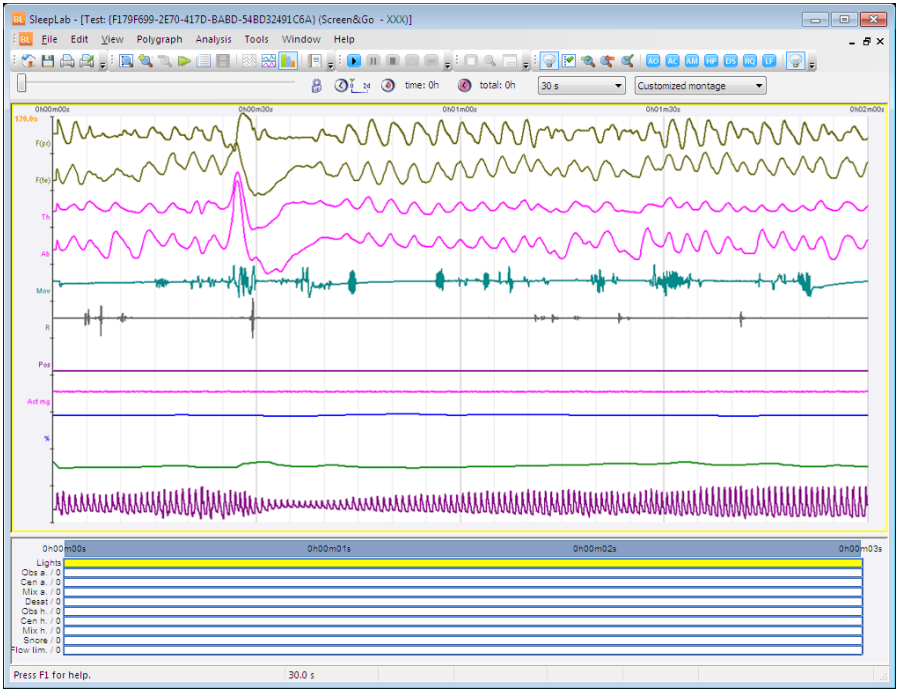
In the General tab, enable the option "Start tests in signal test mode".

Click on Accept to apply the changes.

3.9 REVIEWING THE TESTS

3.9.1 USER INTERFACE ELEMENTS DURING TEST REVIEWS

The following illustration shows the SleepLab software module during a test review:



Menu bar

Standard toolbar: used to access the home screen, save the test and printing.

Test toolbar: communication functions with Sleep&Go during performance of the real-time tests.

View toolbar: changes in the time per epoch, viewing options, report generation, etc.

Play toolbar: allows playing the test at different speeds.

Analysis toolbar: contains tools for sleep event analysis.

Time toolbar: provides a scroll bar to browse through the test. It can also be used to change the time per epoch and the and the montage used.

Waveform window: this window displays the signals recorded by the Screen&Go/Sleep&Go. The screen can be customized in a variety of ways.

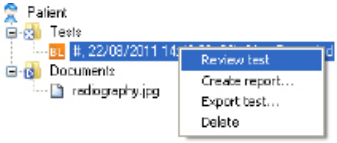
Trend window: this window provides summarized information about sleep events and light status. It provides a summary of the test at a glance.

Status bar: this provides contextual information while the program is being used.

3.9.2 OPENING A TEST

Choose the patient to whom the test is associated or search for the patient using the Search text box.

Display the Test folder in the patient tree. Locate the test to be reviewed and right click to pull down the contextual menu and choose the Review test option.



If the automatic analysis of test events has not been performed, a wizard will start automatically to guide you through the analysis process. If you do not wish to perform the automatic analysis, cancel the wizard.

3.9.3 FULL SCREEN MODE

Use the full screen mode to maximize the available screen space to review the test. The Windows task bar, the title bar of the application and the toolbars will all disappear in this mode (display them by going to the View menu > Toolbars and docking windows).

Go to View > Full screen to enter the full screen mode.

To exit the full screen mode, click on the Close full screen floating button or go to the View menu > Full screen.

3.9.4 DOUBLE WAVEFORM WINDOW

The waveform window can be divided into two parts during review. The two waveform windows can be set up with different time scales. In addition, each waveform can be displayed or hidden in either of the windows. Therefore, for example, in a sleep study the top window can be configured to view the fast channels and the bottom window to display the slow channels, each with a different time range.

The time scale used in the top window is shown in violet over the time scale used in the bottom window.

3.9.5 PLAYING THE TEST

Any of the tests that have already been performed can be played automatically at different speeds:

Place the cursor at the beginning of the part of the test that you wish to play. This can be at the very beginning or any other moment of the test.

Click on the Start playing test button on the play toolbar.

The test will start playing exactly as it was acquired. If you wish to double the playing speed, click on the x2 button (Increase the test playing speed) . If you wish to decrease the playing speed by half, click on the /2 button (Decrease the test playing speed).

You can stop playing the test at any time by clicking on the Pause playing test button . You can start playing the test from the same point where it was stopped by clicking again on the Start playing test.

To stop playing the test, click on the Stop playing test button

. The difference between this button and the pause button is that when play is resumed, it does so from the beginning of the epoch on the screen.

3.9.6 SCROLLING THROUGH THE TEST

Using the time bar

The time bar allows the user to scroll through the test quickly. Simply drag the scroll bar to move to another moment in the test. Scrolling will take place in the window that is active at the time (framed in yellow). The current time and the total duration of the test is shown to the right of the scroll bar.

Using the keypad

The following keys are used to scroll through the test:

Start: moves to the beginning of the test

End: moves to the end of the test

Page down: goes to the next epoch

Page up: goes to the previous epoch

Left arrow ← : goes back a short time in the epoch

Right arrow → : goes forward a short time in the epoch

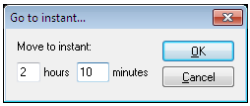
Forward half epoch

Use the Forward half epoch button sdfsdf of the View toolbar or the Tab (tabulator) key to move forward half a epoch. This option is useful for a clear view of events that occur at the limit between two consecutive epochs.

Using the Go to instant option

Open the Analysis menu > Go to instant.

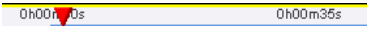
Specify the hour and minute of the test to go to in the box that appears.



Click on Accept for the program to automatically go to the indicated instant.

Using the browsing marks

If there is a place in the test of special interest that you wish to refer to in the future, a browsing mark can be inserted at that place from the Analysis menu > Insert browsing mark, or by pressing on the Ctrl+M key combination. The mark appears as an upside down red triangle on the time scale.



To return to the same point again, simply go again to Analysis > Browse to browsing mark or press on the Ctrl+N key combination.

3.9.7 ADJUSTING TIME ON THE SCREEN

The time scale at the top of the waveform window shows the test time and the size of the epoch. The size of the epoch also appears on the status bar.

Adjust the time on the screen with keys + and - and icons .

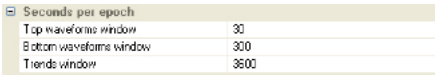
Use the + and – keys to multiply or divide the size of the epoch by two. This can also be done by using the toolbar icons and .

Specifying the number of seconds per epoch

Open the Viewing options window from the Analysis menu > Viewing options.

Enable the Viewing tab. There are three text boxes under the Seconds per epoch tab to set the visible time range in each window (top waveform window, bottom waveform window, trends window). These adjustments can be applied separately to the top

waveform window, the bottom waveform window or the trends window. However, the time range in the top waveform window cannot be longer than that of the bottom waveform window and the time range of the bottom waveform window cannot be longer than that of the trends window.

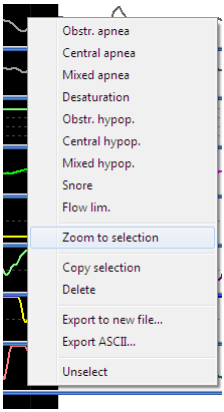


Zooming in on part of the test

Left click on any part of the waveform where you wish to start the enlargement.

Without releasing the left click, drag the mouse to the end of the part that you wish to enlarge.

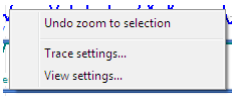
A contextual menu will appear. Select the Zoom selection option.



Undoing the zoom on an area of the test

To undo the zoom on an area of the test, right click on a waveform.

Select Undo zoom selection in the menu that appears.

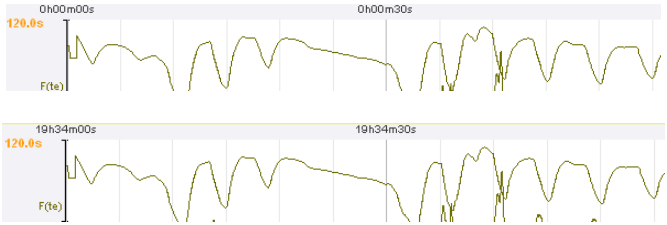


Modifying the time references

The program has two ways to reference time in the various windows:

Reference of the time scale to the instant 00h:00m:00s: the time line begins at instant 0.

Reference of the time scale to the time the test is performed: the time line begins at the time the test recording is started.



Changing these time baselines does not affect the test performance time data.

Go to Analysis menu > Viewing options and enable the Viewing tab.

In the Reference time section, select the instant option 00h:00m:00s or the test performance time option, depending on preferences.

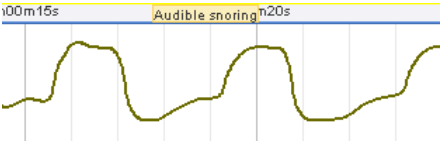
Click on Accept to apply the changes.

3.9.8 NOTES

The user can enter notes throughout the test for important observations. This option can be very useful during performance of the tests in real time to record visual observations regarding the (if the patient is restless, moves or wakes up, etc.) or to record changes in the application of the CPAP, drug administration, etc. All the notes will appear afterwards in the test report, alongside the instant when they were entered.

The program enters a note automatically each time a real-time or holter recording is performed. A note is also inserted each time user events marker pulsing occurs.

These notes are shown on the time scale of the waveform window.



Entering a note

There are two different ways to enter notes:

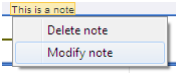
Select Enter note in the Analysis menu.

Press the Insert key on the keypad. A box will appear for the user to enter the text of the note. The user can also choose one of the predefined notes that appear. If the test is in real time, the note will appear overwritten at the instant it is being acquired. However, if a test that has already been acquired is being viewed, the note will appear overwritten at the instant corresponding to the center of the screen being viewed at that time.

Modifying a note

Right click on the note to be modified.

Select Modify note in the contextual menu that appears.

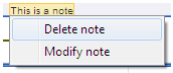


The Enter note window will appear. Modify the text and click on Accept to apply the changes.

Deleting a note

Right click on the note to be deleted.

Select Delete note in the contextual menu that appears.



Showing/hiding notes

Go to the Analysis menu > Viewing options or from the corresponding button of the Viewing toolbar.

Enable the Viewing tab. Enable the Show notes option to show the notes on the screen and disable the option to hide them.

Click on Accept to apply the changes.

Modifying predefined notes

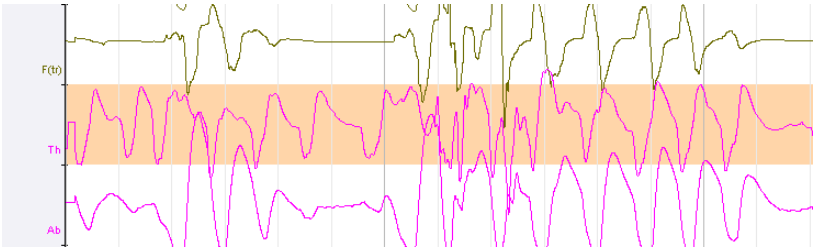
The default text provided by the program when entering notes can be completely customized to user preferences. This is done by editing the notes.txt text file in the application folder (default X:/Program files/Bitmed/BitmedLab x.x). Remember to enter one note per line.

3.9.9 ADJUSTING WAVEFORM RANGES

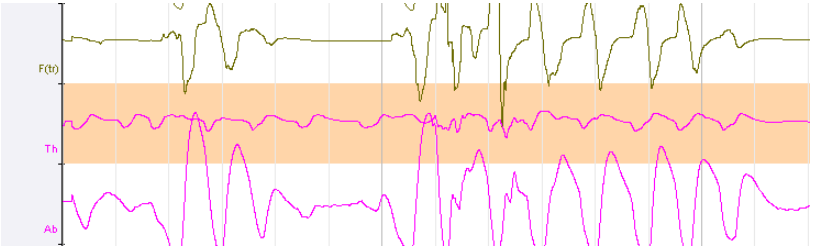
Adjusting ranges with keys ↑ and ↓ or the mouse

The simplest way to quickly adjust the range of a waveform is to place the cursor over the waveform to be changed and press the ↑ and ↓ keys to increase or decrease the amplitude.

If you want to modify the range of more than a waveform at once, then left double click on the waveforms that you wish to change the range of. The background of the waveform will change color.



Use the ↑ and ↓ keys to increase or decrease the range of the selected waveforms.

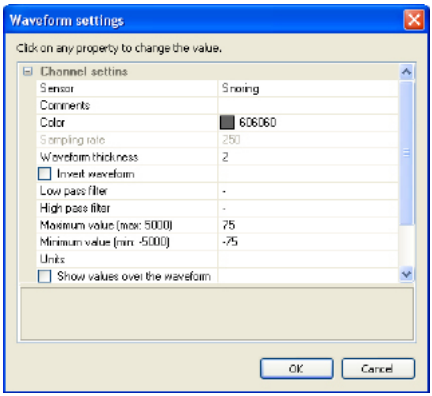


The amplitude of any channel may also be increased or decreased by clicking on it and then pressing the + and - keys, while holding the left mouse button.

Adjusting waveform ranges accurately

Right click on the waveform to be changed and select the Channel setings option.

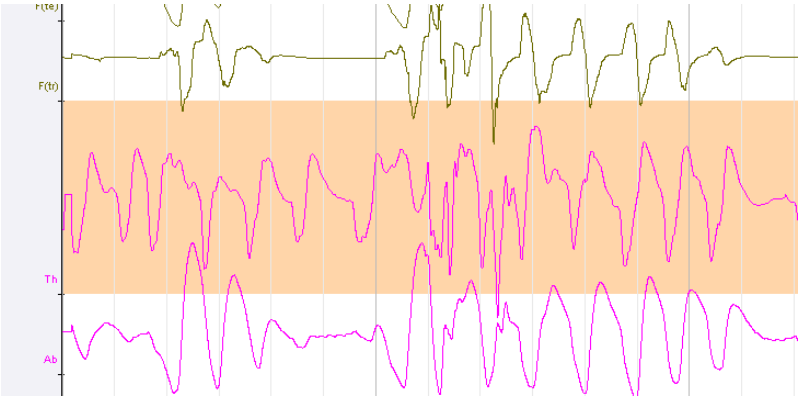
The Channel settings window will open. Change the maximum and minimum values. The possible maximum and minimum values are specified in brackets).



Click on Close when you are done.

3.9.10 ADJUSTING WAVEFORM SIZES

When the cursor passes over the separating lines of the waveforms, it changes to two arrows. This indicates the possibility of dragging the separation line to change the height of the waveform. Pull the line up or down while left clicking to change the height of the waveform to the minimum or maximum height. This functionality can be enabled or disabled from the "Allow changes to the waveform size" option in the Viewing tab in the Viewing options window.

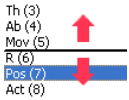


3.9.11 MODIFYING THE VIEWING ORDER OF THE WAVEFORMS

Open the Viewing options window from the Analysis toolbar button or from Analysis menu > Viewing options.

Enable the Montage tab. In the Waveform window list, select the waveform window where the changes to the waveform viewing order will be made (top or bottom).

To change the order of a channel, click on the channel and without releasing the left click, drag it to the new position. Release the left click.



When you have finished adjusting the order of the waveforms,

click on Accept to apply the changes to the test.

3.9.12 NAMING THE WAVEFORMS

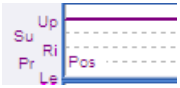
Changing the waveform name display from the Viewing options window

Open the Viewing options window from the Viewing toolbar button or from Analysis menu > Viewing options.

Enable the Viewing tab. Four different waveform name displays are available in the Name section of the waveforms:

Detailed: this includes the full name of the sensor and its description.

Brief: this shows only the abbreviated name of the sensor or the name of the electrode if it is defined.



Off-channel: this is similar to the previous one but shows the name to the left of the channel and hides the scale.

No description: this hides all the text on the waveforms.

When you are finished, click on Accept to apply the changes to the test.

Using the keypad to change the display of the waveform names

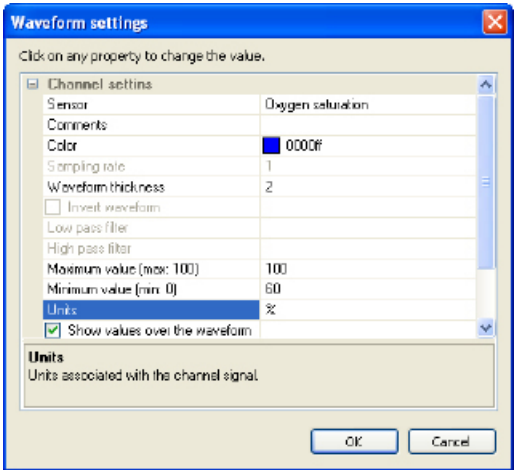
The waveform name display can also be changed by using the keypad. Use the "C" key to scroll through the four display options.

3.9.13 WAVEFORM UNITS

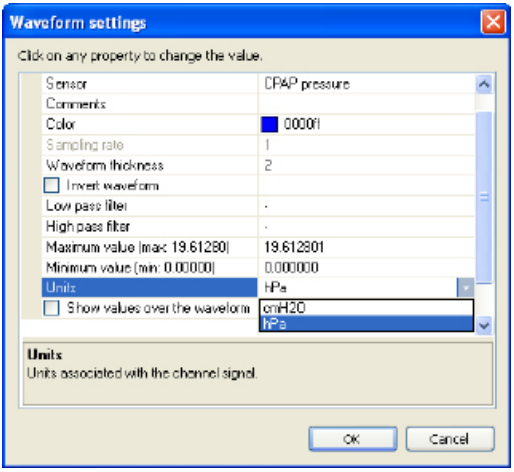
Channels measure physical quantities, such as pulse rate or oxygen saturation. Units are shown in the name of each waveform. You can change the units of waveforms in the following way:

Open the Waveform settings by right clicking the mouse on the channel to be changed and selecting the Waveform settings option in the menu.

In the Waveform settings change the Units property, enter the new text, and click on OK to apply changes.



CPAP channel behaves in a particular way. Two types of units can be selected: hPa and cmH2O. Changing the units automatically updates the minimum and maximum values of the channel. The CPAP channel units should also be changed n the polygraph, as described in the User's manual.

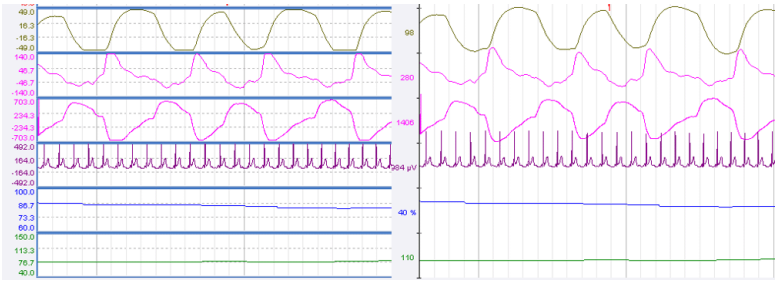


3.9.14 HIDING OR SHOWING SEPARATION BETWEEN WAVEFORMS

Open the Viewing options window from the Analysis toolbar button or from Analysis menu > Viewing options.

Open the Viewing tab and enable or disable the "View separating bar between waveforms" option.

Click on Accept to apply the changes.



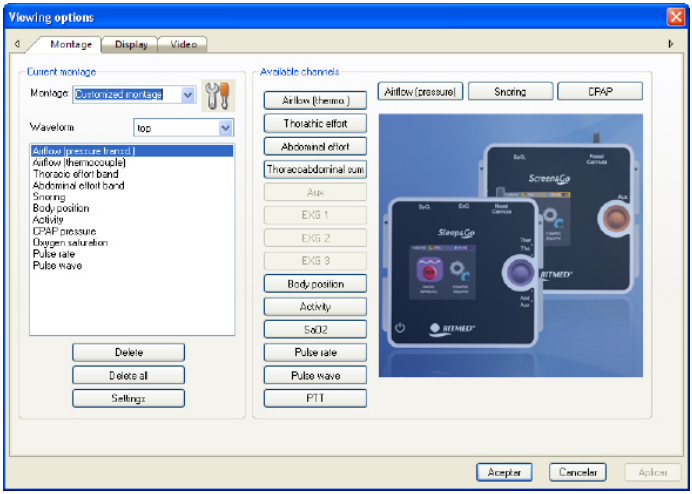
3.9.15 ADDING AND DELETING WAVEFORMS

Adding waveforms

Go to the Analysis menu > Viewing options.

Enable the Montage tab and select waveform view in the Waveform window list (top or bottom) that you wish to set up.

All the inlet channels to the device appear on the right side of the window. Click on the ones you wish to add to the list of channels.



When all the desired channels have been added, click on Accept to close the window and apply the changes.

Deleting waveforms

Go to the Analysis menu > Viewing options.

Enable the Montage tab and select the view you wish to set up from the Waveform window list.

Choose the visible waveforms that you wish to delete from the waveform list.

Click on Delete and the channel will disappear from the list of visible channels.

Click on Accept to close the window and apply the changes.

Deleting all the waveforms

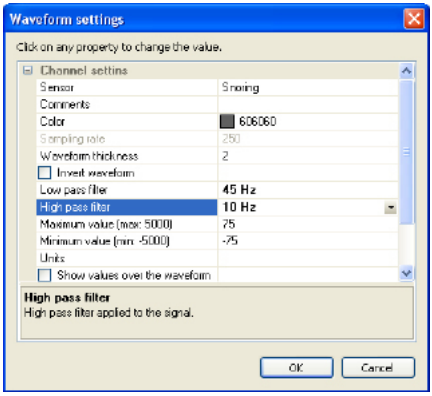
Go to the Analysis menu > Viewing options.

Enable the Montage tab and select the view you wish to set up from the Waveform window list.

Click on Delete all to delete all the waveforms at once. Click on Accept to close the window and apply the changes.

3.9.16 CHANGING THE SOFTWARE FILTERS

Right click on the waveform to be changed and select the Channel properties option.



Choose the low pass and high pass filters you wish to use and click on Accept to apply the changes. Remember that the filters that are available will depend on each channel.

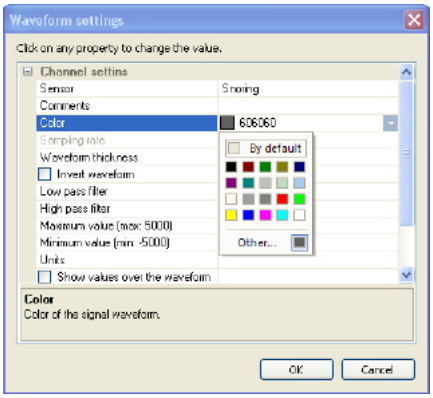
3.9.17 CHANGING THE SIGNAL WAVEFORM COLOR

The waveforms for each type of sensor are given a different color by default, but all these colors can be modified.

In the waveform window, right click on the waveform to be changed and select the Channel properties option.

The Channel properties window will open. There is a Color box with the current color of the signal waveform. Click on the color box to

open the color selection dialog and choose the new color for the signal waveform. Click on Accept when you are done.



3.9.18 MODIFYING WAVEFORM THICKNESS

The on-screen waveform thickness can be modified for all the channels at the same time or only for one specific channel.

Modifying the thickness of all the waveforms

Open the Viewing options window from the Analysis menu and verify that the "Apply the same thickness to all the waveforms" option is selected.

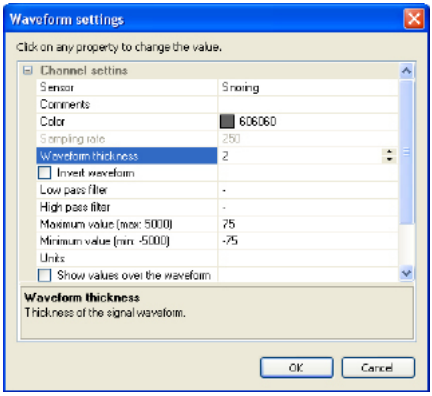
Modify the Waveform thickness option and click on Accept to apply the changes.

Modifying the thickness of a single waveform

Verify that the "Apply the same thickness to all the waveforms" option is not selected in the Analysis window > Viewing options.

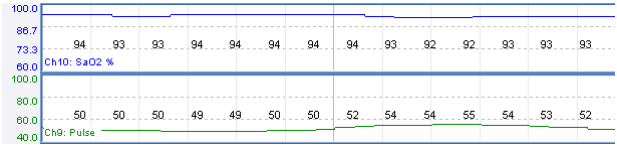
Then open the properties of the waveform you wish to modify by right clicking on it and select the Channel properties option in the contextual menu.

Change the number of thickness pixels and click on Accept to apply the changes.



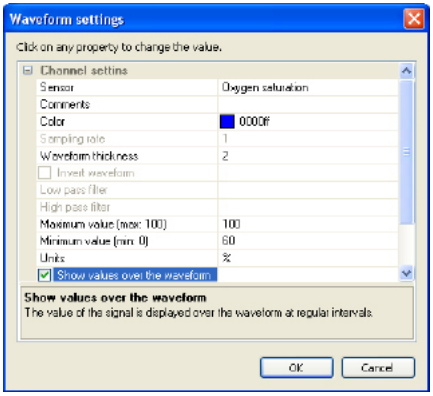
3.9.19 DISPLAYING THE VALUES OVER THE WAVEFORM

Signal values can be displayed on the waveforms at regular intervals.



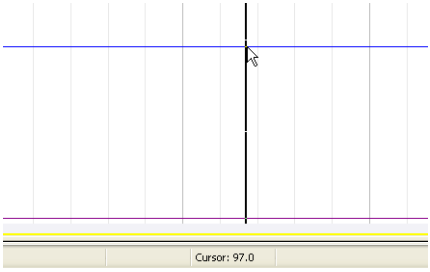
In the waveform window, right click on the waveform to be changed and select the *Channel properties* option.

Enable the *Display values over the signal* option and click on *Accept* to apply the changes.



3.9.20 NUMERICAL VALUES CURSOR

The numerical value cursor is a vertical line that the user can scroll freely across the screen. The status bar shows the value of the signal in the position and the channel that the cursor is on. To display it:

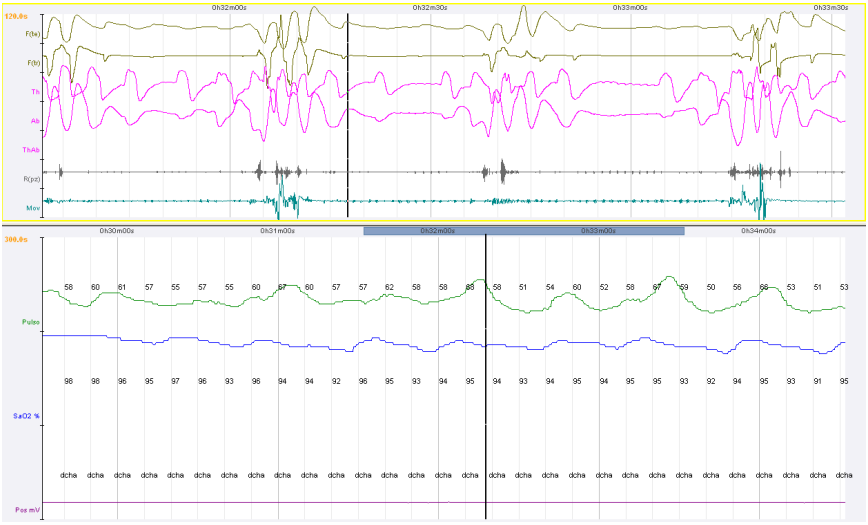


Go to the *Analysis* menu > *Viewing options*.

Enable the *Viewing* tab and mark the box of the *Display cursor* option.

Click on *Accept* to apply the changes.

Once the bottom waveform window is visible, it also displays a cursor that is synchronized with the cursor in the top window, always marking the time instant of the top waveform window.



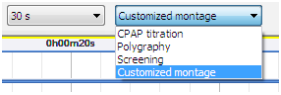
3.9.21 MONTAGES

A montage stores all the settings of a test under a descriptive name. This includes sensors, filters, gains, colors, descriptions, on-screen order, epoch duration, event mark viewing, event bar viewing, channel sizes, etc. In general terms, all the parameters that can be set from the *Viewing options* window are stored in the montage. The montages are stored with a name and can then be loaded and applied to the test at any time during review.

The montages are managed from the *Montage* tab of the *Viewing options* window.The currently selected montage is shown in the *Montage* list as well as in the list of montages in the *Time bar*.

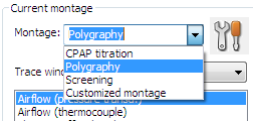
Choosing a montage

The montage can be changed quickly from the waveform window by selecting it from the list in the *Time bar.*



The montage can also be changed from the *Montage* tab of *Viewing*

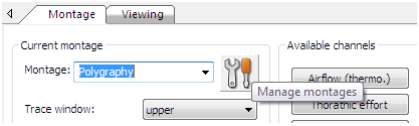
options window.



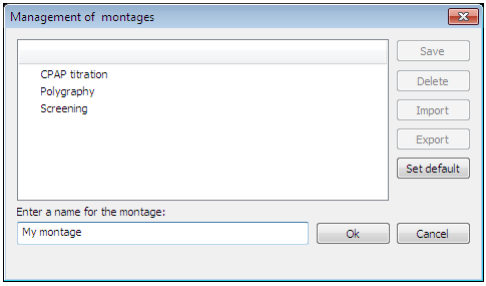
Saving a montage

Once the test has been configured as desired, go to *Viewing options* and enable the *Montage tab.*

Click on the *Manage montages* button.



Click on Save in the *Manage montages* window. The program will request a name for the montage. Enter the name and click on *Accept*. If there is already a configuration with the same name, the program will request confirmation to overwrite it.



Importing and exporting a montage

BitmedLab allows the user to export any of the montages to a file, so that it can be easily imported into another computer.

Go to the *Analysis* menu > *Viewing options*.

Enable the *Montage* tab and click on the *Manage montages* button.

Choose the montage you wish to export from the list of available montages and click on *Export*.

A dialog will appear to choose the name of the file that will store the montage and the folder to save it in.

The montage will be saved in a file with extension *.xcp*

A montage can be imported in a similar manner:

Click on *Import* in the *Manage montages* window.

A dialog will appear to choose the .xcp file corresponding to the montage that is to be imported. The montage will be added to the list of available montages.

Deleting a montage

Go to the *Analysis* menu > *Viewing options*.

Enable the *Montage* tab and click on the *Manage montages* button.

Choose the montage you wish to delete from the list of available montages and click on *Delete*.

3.9.22 TYPES OF EVENTS

BitmedLab defines a series of event types that the user can use in the tests. For user convenience, BitmedLab limit the available event types according to the group of event types that are enabled at a given moment. There are three groups of event types (simple, intermediate and advanced), each of which enables certain types of events, as seen in detail in the table below:

	Simple	Intermediate	Advanced
Obstructive apnea	❍	❍	❍
Central apnea	❍	❍	❍
Mixed apnea	❍	❍	❍
Hypopnea	❍	❍	❍
Desaturation	❍	❍	❍
Snoring	❍	❍	❍
Flow limitation	❍	❍	❍
Limb movement		❍	❍
PLM		❍	❍
Regular breathing		❍	❍
Cheyne-Stokes breathing		❍	❍
Undetermined breathing event		❍	❍
Arousal			❍
Movement arousal			❍
RERA			❍
Tachycardia			❍
Bradycardia			❍
Bruxism			❍

Select a group of event types, depending on the type of test to be performed. For example, the *simple* group may be enough for a screening test, while the *advanced* group may be the proper option for a cardiorespiratory polygraph.

Only one group of event types can be enabled at the same time in the program. In other words, if the *simple* group of event types is enabled and a test is opened with tachycardias marked, the latter will not appear. However, if the group is changed to *advanced*, the tachycardias will be seen perfectly.

Take the following steps to change the group of event types:

Go to the *Tools* menu > *Options.*

Choose the *Event types* tab.

Choose the group you wish to use from the list of *Group of event types*.

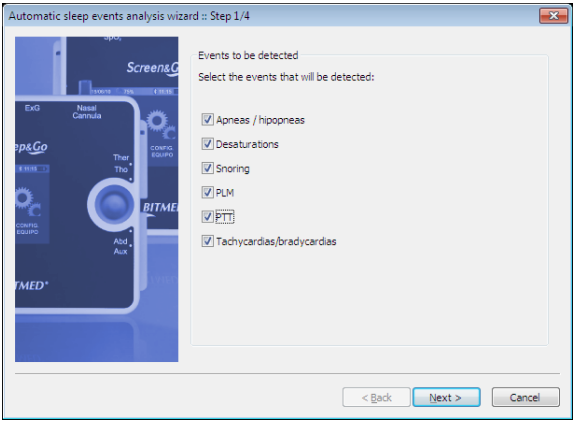
Click on *Accept* to apply the changes.

3.9.23 AUTOMATIC ANALYSIS OF SLEEP EVENTS

	The results provided by the Automatic Analysis of events should not be used as the sole criterion for medical diagnosis or patient treatment. The results must be supervised and reviewed by medical personnel with adequate training.

Go to the *Analysis* menu > *Automatic analysis of events*. The *Automatic analysis of events wizard* will start up.

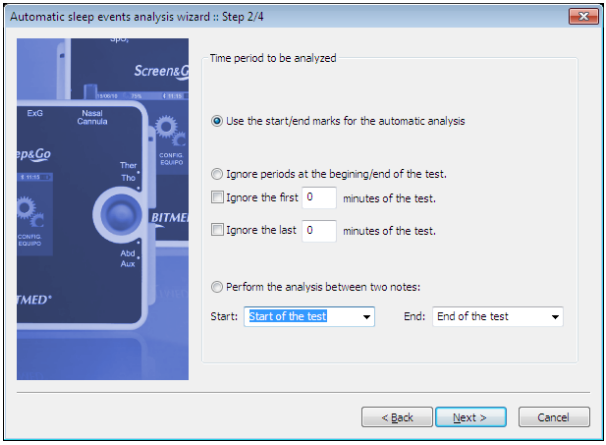
Choose the event types that you wish to detect automatically and click on *Next.*



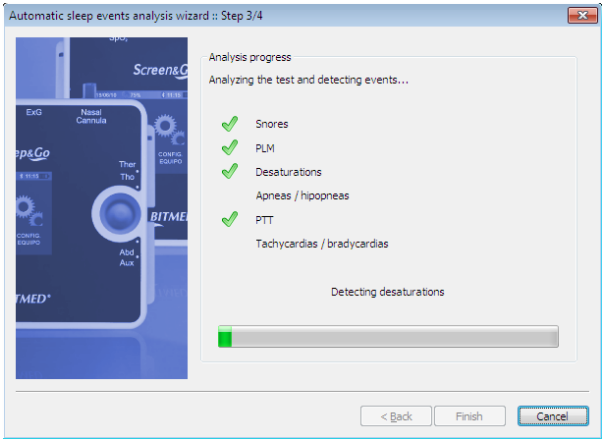
In the next step of the wizard, choose the part of the test that you wish to analyze. If you wish to discard set times at the beginning and/or end of the test, mark the option *Discard epochs at beginning and/or end of the test* and enter the number of minutes to discard in each case.

The test can also be analyzed between any two given marks (see the *Notes* section for insertion of a note in the test), by simply selecting the option *Perform the analysis between two marks*. By default, the program includes marks for *Test start* and *Test end* in order to analyze the entire test.

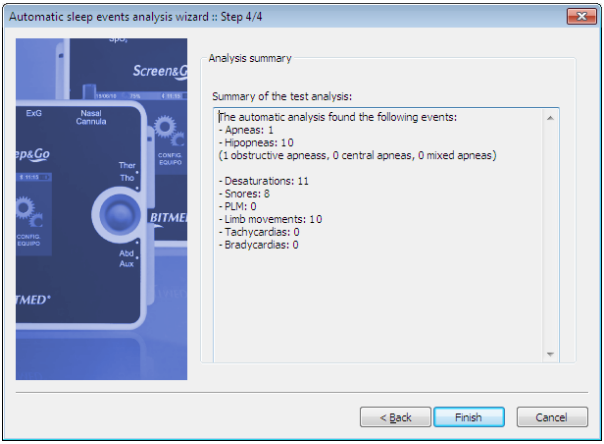
Click on *Next*.


Automatic sleep events analysis wizard :: Step 2/4
Time period to be analyzed
Use the start/end marks for the automatic analysis
Ignore periods at the begining/end of the test.
Ignore the first 0 minutes of the test.
Ignore the last 0 minutes of the test.
Perform the analysis between two notes:
Start: Start of the test
End: End of the test
< Back
Next >
Cancel

The following window shows the progress of the analysis. When the analysis has been completed, click on *Next*.

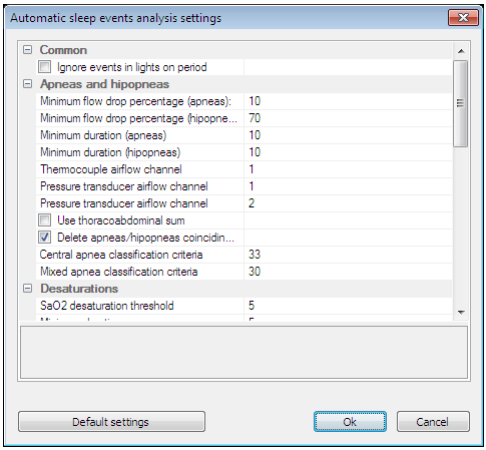


Lastly, the wizard will show a summary of the events that have been detected.



3.9.24 MODIFYING THE OPTIONS FOR AUTOMATIC ANALYSIS OF SLEEP EVENTS

Go to the *Analysis* menu > *Options automatic analysis of events.*



Make the desired changes in the criteria for automatic analysis of events. An explanation of each of these parameters is shown when you click on the parameter. To return to the program default values, click on *Reset default parameters*.

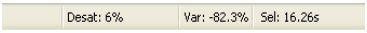
Click on *Accept* to apply the changes.

3.9.25 MANUAL MARKING OF SLEEP EVENTS

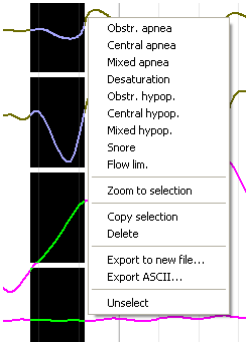
Marking events with the mouse

Place the cursor over any of the waveforms and click on the place where you wish to start the event.

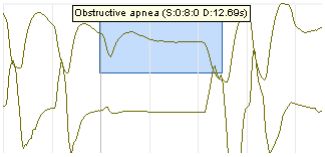
Drag the mouse to mark the duration of the event. The selected duration will appear in the status bar. If you have clicked on an air flow or breathing effort waveform, the desaturation associated with the selection and the signal variation will also be shown. These data are useful for marking apneas and hypopneas.

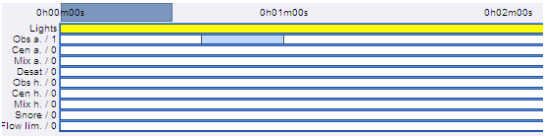


When the selection has been completed, a contextual menu will appear with all the event types. Choose the one you wish to mark.



The event mark will appear. The mark can appear over one or more waveforms, depending on the property settings of the event type. If the trends window is open, a mark will also appear on the corresponding event type bar and the length will depend on the duration of the event. Finally, the number of event occurrences will increase by one.





Marking events with the keypad

Press the key associated with the event. The program will insert a mark starting at the beginning of the epoch on the screen, with a specific duration for this type of event.

Refer to the *Customized keys* tab of the *Settings* (*Tools* > *Options*) window for the key associated to each type of event.

The hotkeys are also listed in Annex 3 in this manual.

Marking event with the mouse and the keypad

Press on the key associated with the event that you wish to mark. The cursor changes to an arrow with the sign +.

Do not release the key and select the part of the test where you want to mark the event.

Release the key to mark the event.

There is another way to mark events with the keyboard and mouse: Press the key next to the event you want to dial, and then click the mouse in the place where the event starts. The program inserts a predetermined duration event

Use the event marking toolbar

Choose the type of event that you wish to mark.

The cursor changes to an arrow with the sign +. Unless you click again on the event type icon, all the events that are marked will be of the same type.

Do not release the left click and select the part of the test where you wish to mark the event.

Release the left click to mark the event.

3.9.26 WORKING WITH EVENTS

Modifying the default duration for events inserted with the keypad

Open the window *Tools* > *Options* > *Event types*.

Choose the event type you wish to customize and click on *Properties.*

Enter the desired duration with all the occurrences of the event entered with the keypad in the text box *Default duration of events entered with the keypad*.

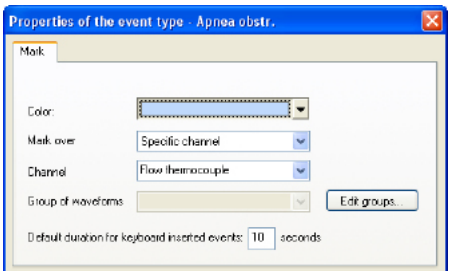
Click on *Accept* and close the *Event types* window.

Changing the color of the event marks

Open the window *Tools* > *Options* > *Event types*.

Choose the event type you wish to customize and click on *Properties.*

Click on the *Color* section and choose the desired color for the mark.



Click on *Accept* to apply the changes.

Hiding/showing the event marks on the waveforms

The events are marked with a color rectangle over the signal waveform. The mark also includes the event type, the time instant of the start of the event and its duration. These marks can be shown or hidden by the user.

Open the *Viewing options* window from the *Analysis* menu and enable the *Waveforms* tab

To hide the marks, disable the option *Show event marks on waveform*. Enable the option again to show the marks.

Click on *Accept* to close *Viewing options* and apply the changes.

Hiding/showing the trends window

The trend window displays a bar for each type of event. The occurrence of each event is marked with a color rectangle on this bar. The number of occurrences of each event type appears on the left of each bar.

These bars are normally used to get a general idea at a glance of the trend of events over a long epoch of the test or the complete test. The trends window can be shown or hidden by clicking on the button of the *Viewing* bar or by clicking on the *See* > *Trends* menu.

Moving events

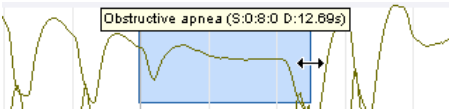
Place the cursor over the event to be moved. The cursor changes as shown in the illustration.

Click on the event and drag it while left clicking.

Release the left click when the event mark is in the desired position.

Changing event duration

Place the cursor over the left or right end of the event. The cursor changes as shown in the illustration.

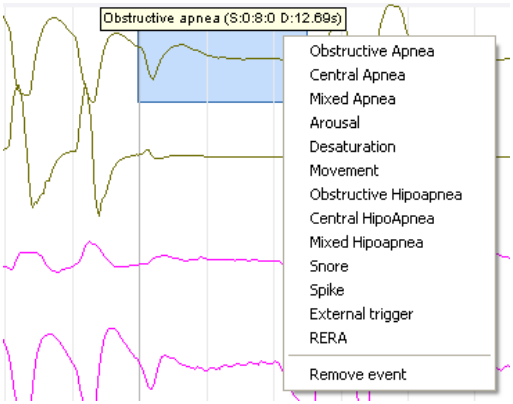


Click and move the cursor to the left or right, while maintaining the left click.

Release the left click when the event mark is in the desired position.

Changing event types

Place the cursor over the event you wish to change and right click. A menu will appear with all the event types defined in the application.



Choose the type of event to assign to the event.

Deleting events with the mouse

Press the *Control* key. The cursor changes to an arrow with the sign -.

Do not release the *Control* key and click on the event to be deleted.

Deleting events from the event mark

Place the cursor over the event you wish to delete and right click.

Choose the *Delete event* option in the contextual menu.

Deleting all the test events

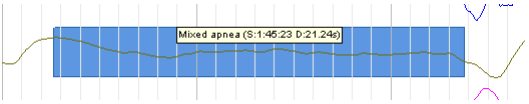
Choose the *Delete all events* option in the *Analysis* menu.

Confirm that you wish to delete all the test events.

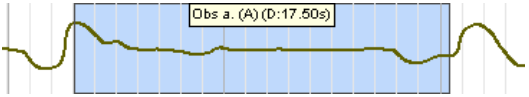
Changing the way the event marks appear on the screen

The event marks on the channel waveforms can be viewed in different ways:

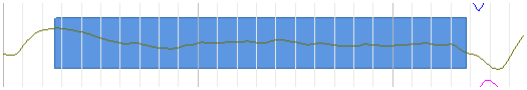
Detailed: a legend appears on the mark that includes the event type, the initial instant and its duration.



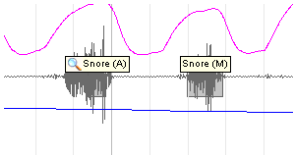
Brief: a legend appears on the event mark only with the short name of the event type and the duration.



No description: no text appears. The event type is distinguishable only by the color of the mark or the waveform on which it appears.



Events inserted manually show the mark *(M),* while events detected by automatic analysis show the mark *(A)*.



Toggle between the three views by using the "E" key or from *Viewing options*:

Open *Viewing options* from *Analysis* > *Viewing options* and enable *Waveforms*.

Choose the option you wish to use in *Event mark descriptions*.

Click on *Accept* to close the window and apply the changes.

3.9.27 CALCULATING THE PTT

The Sleep&Go polygraph allows acquisition of the ECG signal (using the optional ExG channel module) and pulse wave (optional in model A and serial in model B). These two channels generate a third, calculated channel: the PTT (Pulse Transit Time). This channel shows the time it takes the pulse wave to travel between two arterial points, in this case between the place of acquisition of the ECG signal to the tip of the finger, where the pulse oximeter is placed. This is a calculated channel that displays 0 during performance of real-time tests and that the program has to calculate once the test has finished.

Perform the test, making sure to correctly place a pair of ECG electrodes, the patient's ground electrode and the pulse oximeter. Remember to acquire the ECG and pulse wave channels.

Once the test is finished, go to *Analysis* > *Calculate PTT*. The program will calculate the PTT data and update the PTT waveform.

To perform the calculation, the program uses the ECG channel selected in the automatic analysis options (*Analysis > Automatic analysis options*).

If the PTT waveform is not visible on the screen, it can be shown as any other waveform by going to *Analysis > Viewing options,* enabling *Montage* and clicking on the *PTT* button.

In the report, the program will show a series of data associated with the PTT, such as the number and rate of increases, decreases, maximum and minimum values, etc.

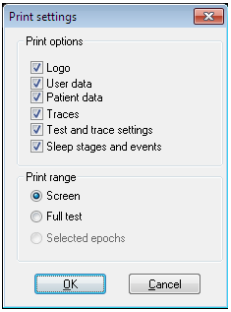
3.9.28 PRINTING

The SleepLab software module allows the user to print both the epoch being viewed on the screen and a selection of several epochs (consecutive or not) or the entire test.

Printing the on-screen epoch, the entire epoch or a selection of epochs.

Browse to the epoch you wish to print and go to *File > Print.*

Choose the printed items to include in the dialog. For example, a header with user data and/or logo can be added.



Choose the printing range and click on *Accept*.

Direct printing

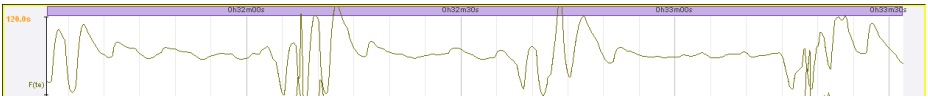
The epoch on the screen can be printed directly by simply clicking on *Direct printing* in the *Standard toolbar*. The epoch will be

printed with the last settings used to print from *File* > *Print.*

Choosing epochs for future printing

While reviewing the test, a series of epochs can be selected to be printed at the same time.

Choose the epoch on the screen by clicking on *Select for printing* . The epoch is selected and distinguished from unselected epochs by a purple mark in the time scale area.



When you have finished choosing the epochs, go to *File* > *Print* and when the *Printing options* window appears, choose *Selected epochs* in *Printing range*.

Preliminary printing view

Go to *File* > *Preliminary presentation*.

Choose the items you wish to include in the preliminary view. This window also provides the option of obtaining a preliminary view of the entire test, only the epoch viewed on the screen or the epochs selected for printing.

The preliminary view can be used to print what is being viewed on the screen.

3.10 GENERATING REPORTS

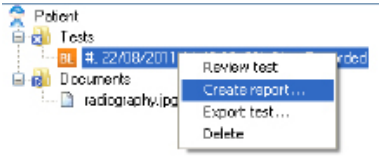
Once the doctor has reviewed the test, he can issue a complete report with all the test data, including statistical information of the sleep events that have been detected.

The software includes a series of default templates that can be used to generate reports. The user can customize these templates or create new ones, as described below.

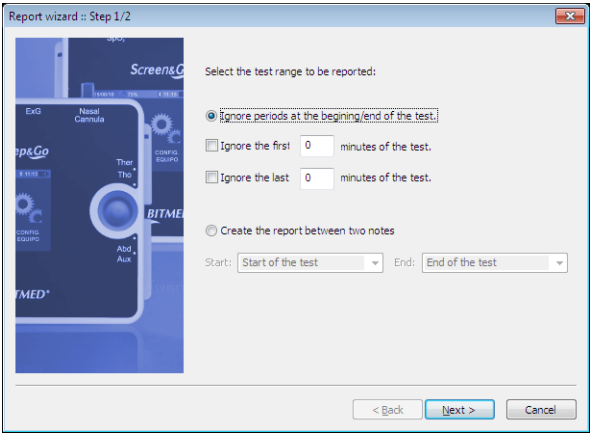
3.10.1 GENERATING A REPORT

To generate a report from the database:

Choose the patient, right click on the test from which to generate the report and choose *Create report*.

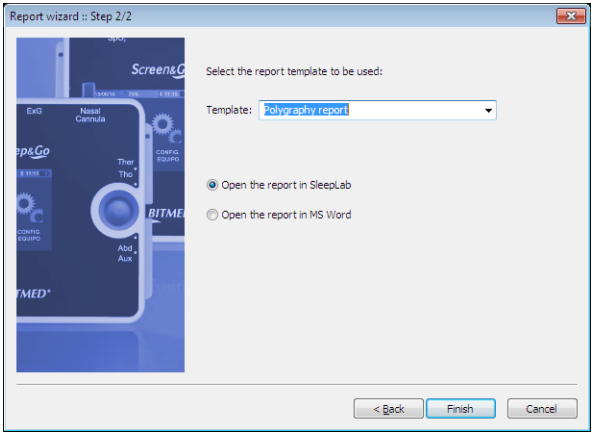


The report generation wizard will start-up. The user can choose the range of the test to take into account for the calculation of all the statistical data of the test. The user can also discard a epoch at the beginning and/or end of the test or perform calculations between two marks (notes). Choose what you wish to do and click on *Next*.



In the next step, choose the report template to be used. Any new template generated will be added automatically to this list.

The user can also choose that the report open directly in the software or in the MS Word text editor (if it is installed in the system).



To generate a report when the test is open on the screen:

Choose *Report* in the *See* menu. You can also use the button.

The *Report creation wizard* will be launched. Follow the steps indicated previously.

If the test is edited after generating the report, the report will have to be generated again for the changes to appear.

3.10.2 PRINTING A REPORT

With the report open and activated on the screen, go to *File* > *Print.*

Choose the printer, printer properties, printing interval and number of copies.

Click on *Accept* to start printing.

3.10.3 SAVING A REPORT

Go to *File* > *Save.*

In *Save as*, enter the name of the report file, choose a folder to save it in and click on *Save*.

3.10.4 CHOOSING THE REPORT EDITOR

By default, the report will appear in a window in SleepLab. If you wish, SleepLab can open the report automatically in MS Word, which provides much better editing possibilities.

Take the following steps to change the report editor:

Go to the *Tools menu* > *Options.*

Enable the *Edit reports in MS Word* in the *General* tab.

Click on *Accept* to close the window and save the changes.

3.10.5 GENERATING AND MODIFYING REPORT TEMPLATES

The program is provided with several different report templates, designed for different types of tests. However, the user can generate new templates or customize the existing templates to adjust them to his needs.

The report templates are in the *Templates* folder of the BitmedLab software product line folder (e.g.: C:/Program Files/Bitmed/BitmedLab 1.0/Templates).

The report templates are in RTF format. RTF is a universal file type for text formatting. The WordPad program, supplied with Windows or MS Word, two common programs, can work with this type of file.

Any of the templates saved in this folder can be used to generate a new report. All that is required is to create a new template and save it in the *Templates* folder, where it will be available for the generation of a new report.

The report templates are based on the use of a series of labels that are later interpreted by SleepLab to generate the reports.

For example, if a line in the template is:

Name: #name_pat#

the program will replace the #name_pat# label with the real name of the patient so the report shows something similar to the

following:

Name: Paul Garralda

If, on the contrary, the template has:

Total recording time: #TRT# min

the generated report will replace the #TRT# label with the total recording time:

Total recording time: 182 min

Any of the report templates supplied by default with the program can be opened in your usual text processor to verify its appearance.

Refer to the CD supplied with the software to familiarize yourself with the complete list of available labels to customize your reports.

Briefly, the steps to create a report template are as follows:

Open a word processor, such as WordPad or MS Word.

Create a new document or edit any of the report templates in the *Templates* folder.

Customize the report. You can use, tables, format the text (bold, various fonts, colors), insert images, etc. The text entered will appear the same in the report, while the labels with the #name_label# format will be automatically replaced with a value calculated by the program.

When you have finishes, save the file with the .RTF extension in the *Templates* folder.

The new template will appear in the list of available templates for the generation of reports.

4. USING THE PROGRAM WITH THE EXEA SYSTEMS

4.1 BEFORE STARTING

4.1.1 START THE PROGRAM

There are two ways to start the program:

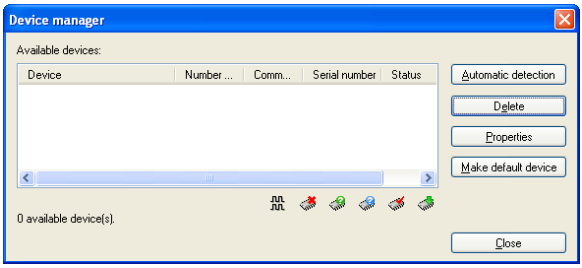
On the Windows Desktop, double click on the *SleepLab Pro* icon.

In the Windows *Start* menu, click on *All programs,* go to the *BitmedLab* folder and click on the *SleepLab Pro* icon.

4.1.2 REGISTERING THE EXEA IN THE SOFTWARE

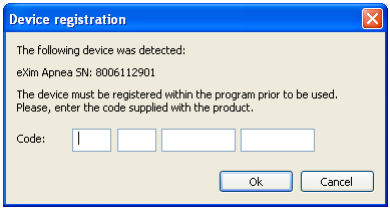
Before starting to use the eXea, it must be registered in the BitmedLab software. This procedure is required only once and ensures that your program is aware of the characteristics of your computer and those of the optional modules you have purchased.

Go to the *Device* menu > *Device manager.*

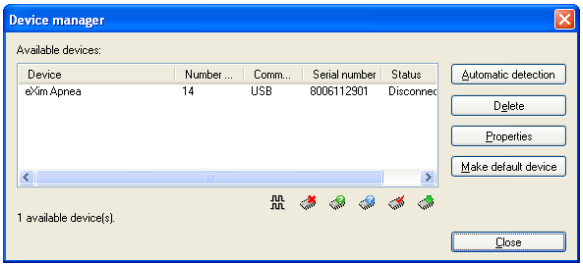


Make sure the eXea system is running and connected to the PC. Click on *Automatic detection*. The software will detect the connected device.

A window will open to enter the password provided with your copy of the BitmedLab software.


Device registration
The following device was detected:
eXim Apnea SN: 8006112901
The device must be registered within the program prior to be used.
Please, enter the code supplied with the product.
Code:
Ok
Cancel

Verify that the device has been registered in the software and that you can now work with it.

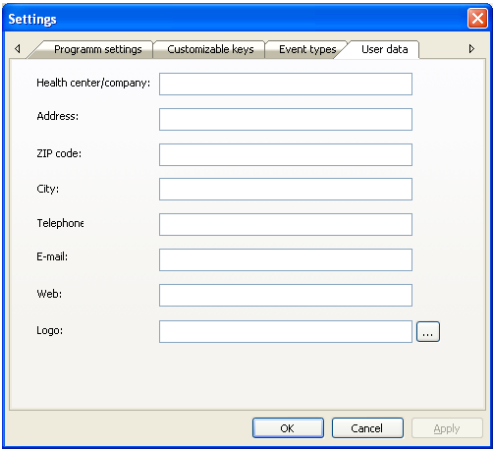


4.1.3 ENTERING USER DATA

BitmedLab lets you enter user data and a logo. These will appear in the header of printed documents and of the report generated for each test.

Go to the *Tools* menu > *Options.*

Open the *User data* tab and fill in the fields of the form.



To select a logo, click on the "…" key of the *Logotype* field and choose your logo image. The image must have been stored in a file with BMP format.

4.2 MANAGING PATIENTS AND TESTS: THE DATABASE

The BitmedLab database provides easy management of all your patients and tests. It can be accessed by clicking on the *Database* button of the *Standard toolbar.*

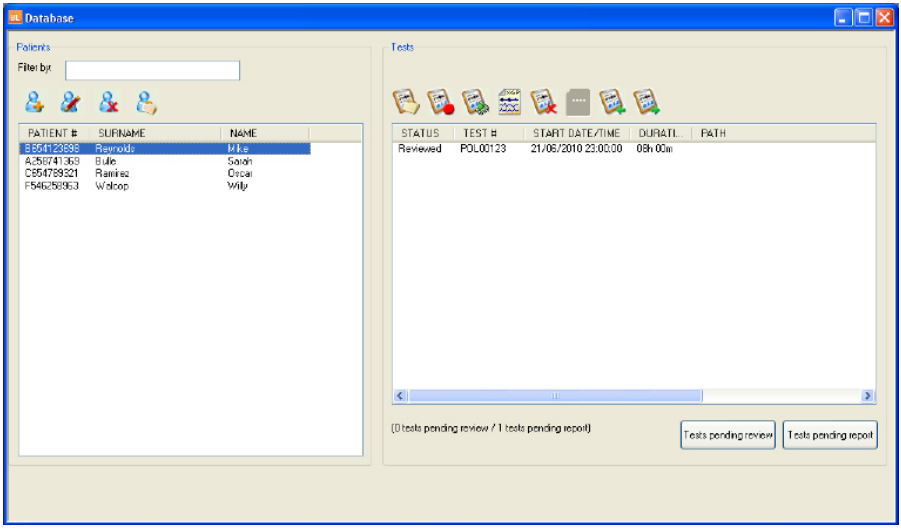
The database window is divided into two highly differentiated areas. On the left is the list of patients, showing the name, last name and number of the patient. The list can be ordered by any of these fields by clicking on the field header.

Over the field header are the buttons used to add, change or delete a patient, or to show the patient's associated documents. There is also a text box to browse through the database.

The area on the right is used to show the tests associated with the patient that has been selected. The information is updated every time a different patient is selected. Each test includes the start date and time, duration and status of the test. The buttons at the top are used to review tests, generate new tests in real time or to download tests to the computer, import, export, etc.

Lastly, there is information concerning the test pending review or

reporting, as well as buttons to access these quickly.

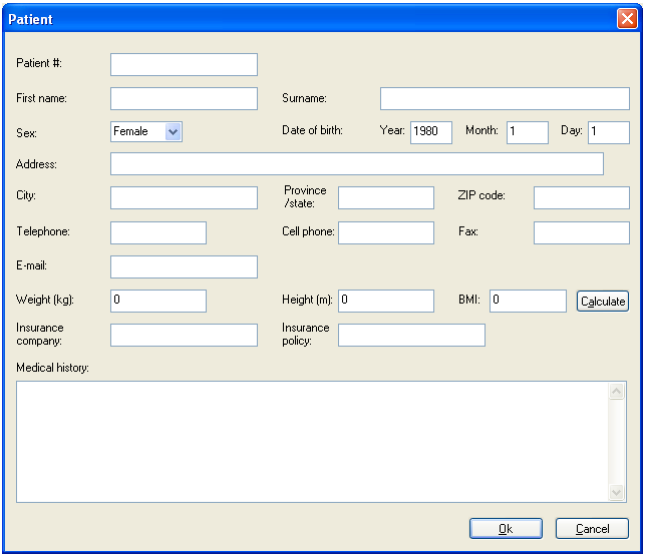


4.2.1 ADDING, MODIFYING AND DELETING PATIENTS

Adding a new patient

Have the database window open and click on the *New patient* button .

Fill in the patient data in the *Patient* window and click on *Accept*.



Modifying an existing patient

Have the database window open, select the patient to edit from the patient list and click on the *Edit patient* button .

Edit the patient data in the *Patient* window and click on *Accept*.

Deleting a patient

Have the database window open, select the patient to delete from the patient list and click on the *Delete patient* button .

Confirm that you wish to delete a patient.

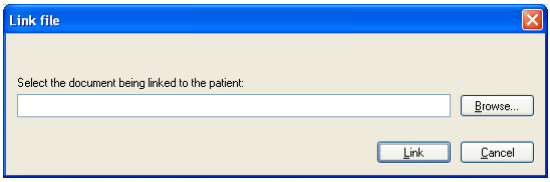
4.2.2 ASSOCIATING DOCUMENTS TO A PATIENT

The user can associate documents of any kind to a patient, such as images, text documents, PDF files, etc.

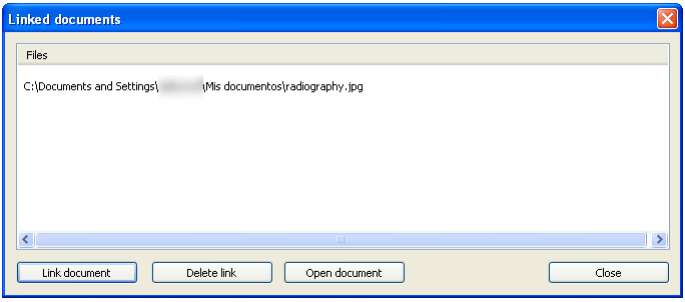
Have the database window open, select the patient to associate to a file and click on the *Associated documents* button .

Click *Associate file* in the *Associated files* window.

Click on the *Browse* button in the *Associate file* window and choose the file that you wish to associate with the patient.



The file appears listed in *Associated files*.

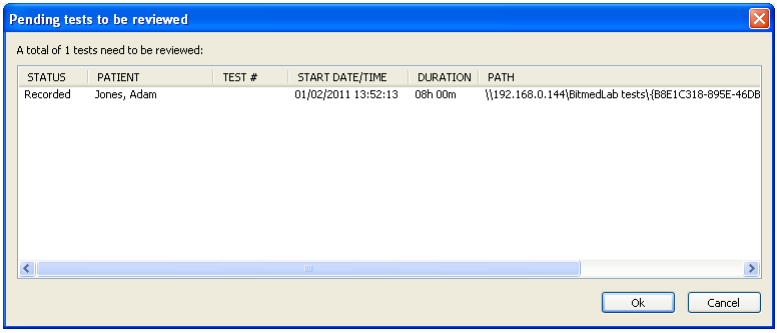


4.2.3 SEARCHING IN THE DATABASE

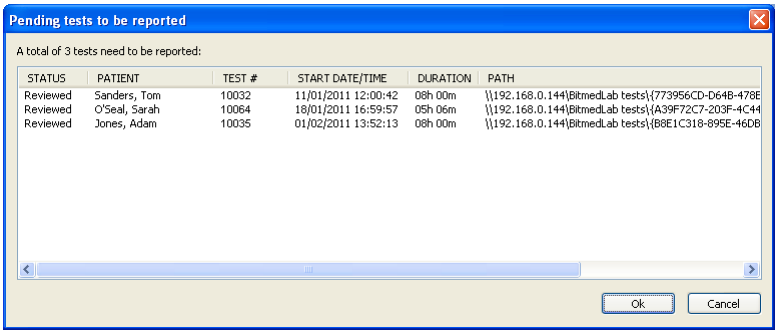
Use the *Search* field of the database window to filter the patients shown in the list. For example, you can search for a specific patient by entering the last names in the search field.

4.2.4 TESTS PENDING REVIEW OR REPORT

The *Tests pending review* button displays a window with the list of all the tests that have been downloaded to the PC and have yet to be reviewed.


Pending tests to be reviewed
A total of 1 tests need to be reviewed:
STATUS PATIENT TEST # START DATE/TIME DURATION PATH
Recorded Jones, Adam 01/02/2011 13:52:13 08h 00m \\192.168.0.144\BitmedLab tests\{B8E1C318-895E-46DB
Ok
Cancel

On the other hand, the *Tests pending reports* button is similar to the one above, but in this case it lists the tests that have been reviewed but for which a report has not yet been generated.


Pending tests to be reported
A total of 3 tests need to be reported:
STATUS PATIENT TEST # START DATE/TIME DURATION PATH
Reviewed Sanders, Tom 10032 11/01/2011 12:00:42 08h 00m \\192.168.0.144\BitmedLab tests\{773956CD-D64B-478E
Reviewed O'Seal, Sarah 10064 18/01/2011 16:59:57 05h 06m \\192.168.0.144\BitmedLab tests\{A39F72C7-203F-4C44
Reviewed Jones, Adam 10035 01/02/2011 13:52:13 08h 00m \\192.168.0.144\BitmedLab tests\{B8E1C318-895E-46DB
Ok
Cancel

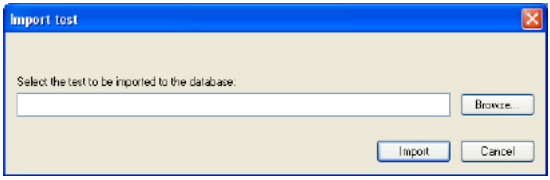
These two functionalities make it easier for the user to find work that is still pending. Double click on any of the tests to open them.

4.3 IMPORTING AND EXPORTING TESTS

Importing tests

Select the patient to whom you want to add the test and click the Import test button .

In the Import dialog box, select the test file to be added using the Browse button and click on Import. The test will be added to the patient.



Exporting tests

To export a test select it in the database and click the Export test button .

In the Save As dialog box select the name and path to the file where the file will be saved.

4.4 PERFORMING THE TESTS IN REAL TIME

A test in real time is a test that is performed while the device is connected to the computer, so that the biomedical signals that are acquired are viewed in real time on the computer screen.

	Do not turn off the PC when performing a real-time test. Stop the real-time test first.

The tests are stored in the hard disk of the computer, in a file with .xgp extension. However, for security reasons, the test is also stored in the internal memory of the device, as long as there is enough available space.

Video synchronized with the biomedical signals can also be captured to improve patient monitoring. In this case, it is generated in the same folder where the .xgp file is stored, in a file with .avi extension and the same name as the test file.

Capturing digital video involves a large amount of free space in the hard disk, which determined by the resolution and the number of frames used for capturing.

We recommend having at least 20 Gb free to perform a long sleep test.

Capture of digital video is not available in tests performed in holter mode.

4.4.1 STARTING THE REAL-TIME TEST

The test is started in the program once the electrodes and sensors have been placed on the patient.

Choose the patient to whom the test is associated with in the database window. If the patient is not in the database yet, enter the patient data first.

Click on *New real-time test* .

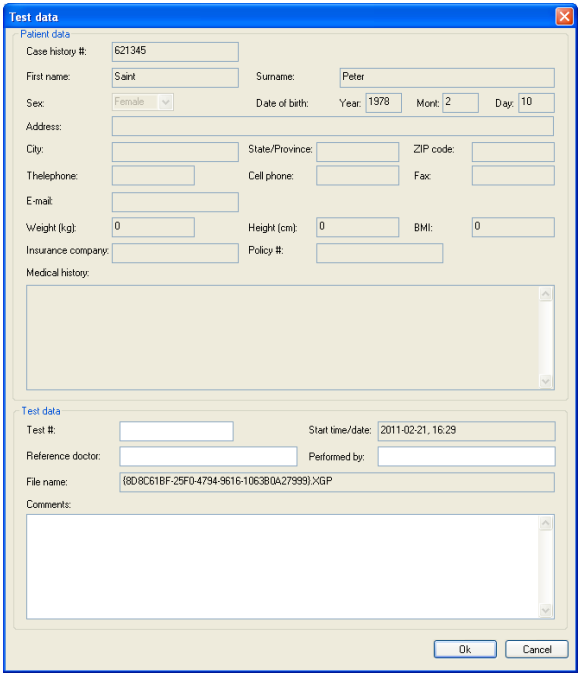
If there is more than one device, you are requested to indicate which device is going to be used to perform the test.

The *Viewing options* dialog box appears. Enter the test settings options, the sensors that are going to be used, the screen viewing order, filters, epoch durations, etc.

Though these data can be customized each time a new test is started, it is more convenient to save all the parameters under a *default configuration*, that can be then loaded directly or used by default for all the new tests to be performed. You can find more information on managing default configurations further along in this manual.

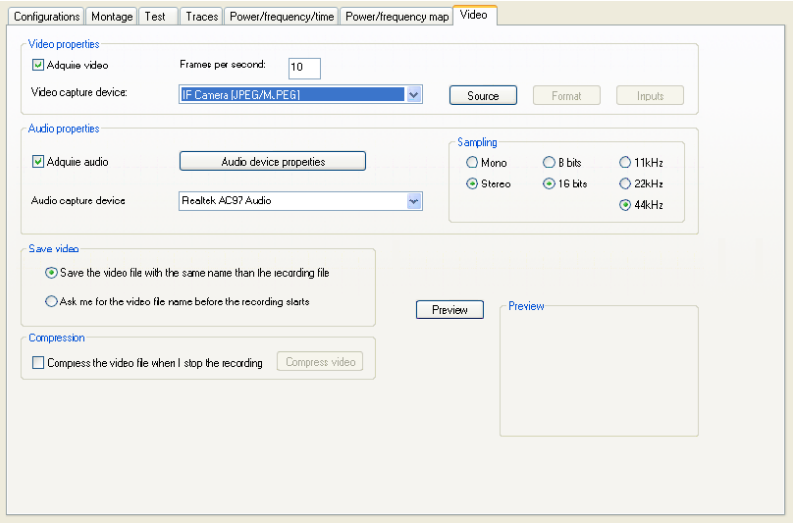
To apply an existing setting or a different setting than the default setting to the test, choose it from the list and click on *Read setting.*

Enable the *Test* tab and click on *Test data.* A dialog will open for the user to enter the test data. Click on *Accept* when you are done. The user can return at any time to edit the data contained in this window by accessing *Viewing Options* and *Test*.



If you wish to check electrode impedances, enable the *Measure impedances before starting a new test* box in the *Test* tab. You can also enable the *Measure impedances before continuing test acquisition* option if you wish to check the impedances each time you pause and resume test recording.

If you have the license of the XGPVision optional software module and wish to capture digital video, enable the *Vídeo* tab. This tab will not appear if the XGPVision module is not available.



Set up the video and audio acquisition options according to your preferences. You can find more information on video and audio acquisition further along in this manual.

Click on *Accept* to close *Viewing options*.

The software will ask you to choose the name to save the test with. Choose the folder and the name you wish to save the new test with and click on *Save*.

The device will start acquisition of the biomedical signals and they will be displayed on the screen in real time. The data will also be stored in the internal memory of the device.

4.4.2 PAUSING AND RESUMING A TEST

The test can be paused and resumed momentarily at any time.

Click on the button or go to *Communication* > *Pause/continue test*.

Test acquisition will stop. If a test with video capture is paused, the video window will also pause, therefore, if you move through the test the video will not synchronize with the time instant being

viewed. This feature is accessed by stopping the communication with *End test* . However, the user should take into account that once a test with video has been completed, it cannot be continued.

To continue the test from the point at which it was paused, click again on the same button or on the same menu option.

4.4.3 COMPLETING TEST ACQUISITION

Click on the button or go to *Communication* > *End test*.

The test recording will stop after a few moments and the device will stop recording data in the memory card.

If a test that includes video capture finalizes, the recording cannot be continued afterwards. Once the test is completed, the test can be reviewed and the video will synchronize fully with the time being viewed.

4.4.4 MEASURING IMPEDANCES

During real-time test performance, electrode impedance can be checked at any time.

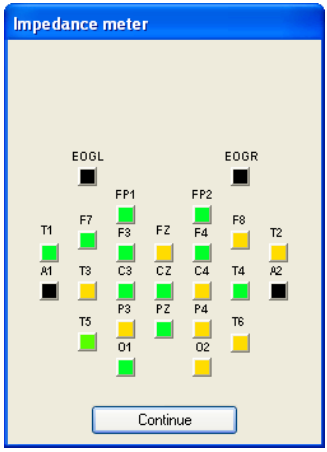
Click on *Measure impedances* Ω in the *test toolbar*. A window will appear showing the impedance of each electrode, according to the following color code:

Black: the electrodes in the air and impedance is higher than 80 kΩ. Very poor contact.

Red: impedance between 22 kΩ and 80 kΩ. Poor contact.

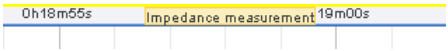
Yellow: impedance between 6.5 kΩ and 22 kΩ. Regular contact.

Green: impedance under 6.5 kΩ. Good contact.



Place the electrodes again as needed and click on *Continue* when finished.

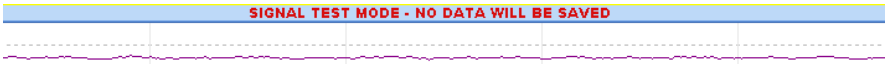
A note will be inserted in the test indicating the instant when impedances were measured.



4.4.5 SIGNAL TEST

Entering and exiting the signal test mode while the test is being performed

At any time during the performance of the test, the user can use the *Signal test* button on the *Test* toolbar to momentarily stop recording the data from eXea in the PC. However, the biomedical signals will continue to be displayed on the screen. Use this option, for example, to relocate a sensor that has moved or been placed incorrectly and to check changes in the sensor signal, without any of it being stored in the test.



To continue the test from the point at which the signal test had begun, click again on the same button.

Start all the tests in signal test mode

For any new real-time recording to start automatically in the signal test mode, take the following steps:

Go to the *Tools* menu > Options.

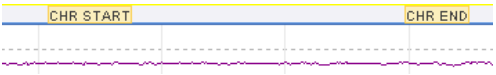
In the *General* tab, enable the option *Start tests in signal test mode*.

Click on *Accept* to apply the changes.

4.4.6 USING THE TIMER IN REAL-TIME TESTS

The software has a timer that can be used to time the various events or parts of a test. For example, the user can control the time during which the patient should hyperventilate, according to the protocol being used.

When the timer is launched, a note reading CR START is automatically inserted in the test. Likewise, when the timer is stopped, a note reading CR END is inserted.



The timer appears on the right of the status bar and can only be used while recording is being acquired in real time.

Starting/Stopping the timer

Press the SPACE key to start the timer count.

Press the SPACE key again to stop the timer. The timer can be started and stopped as many times as you wish during the test.

4.5. PERFORMING TESTS IN HOLTER MODE

A test in holter mode is a test during which the Bitmed eXea system is not connected to the computer while the test is being performed. The data are stored in the internal memory of the device and once

the test is completed, they are transferred to the computer for review.

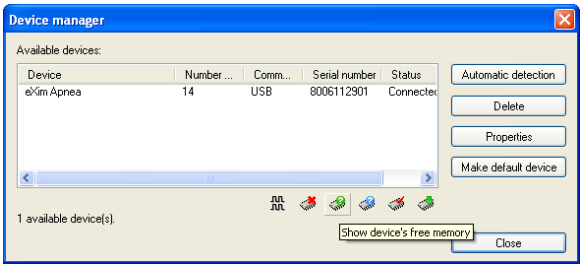
More than one holter mode test can be performed consecutively. Afterwards, when the data are downloaded to the PC, they can be separated into the several different tests that were actually performed.

Capture of digital video is not available in tests performed in holter mode.

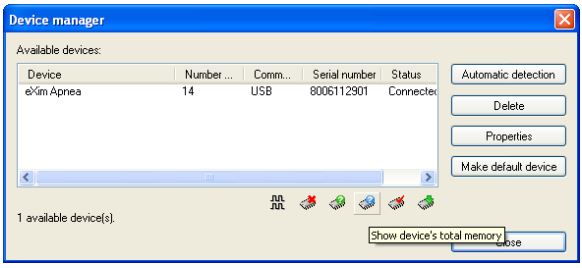
4.5.1 CONSULTING DEVICE FREE/TOTAL MEMORY

Go to the *Device* menu > *Device manager.*

In *Device manager* click on *Show device free memory* so see how many hours of storage are still available in the internal memory of the device. If more memory is needed, make sure all tests already performed have been downloaded to the PC and delete the information remaining in the memory.



To consult the total number of hours that the device can record in holter mode, click on *Show device total memory.*



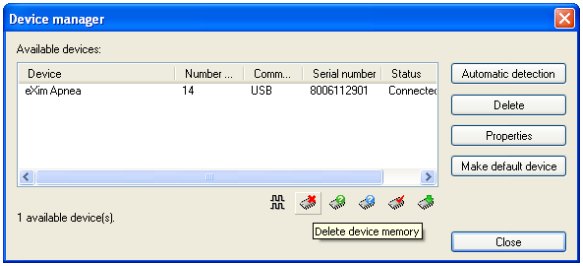
4.5.2 DELETING THE DEVICE MEMORY

Before starting a test in holter mode, it is recommendable to delete the contents in the device memory. This ensures that there is enough space in the internal memory of the device for the new test.

	Before deleting the contents of the device memory, make sure that all test that you are interested in keeping have been downloaded to the PC. The deletion procedure will eliminate all the tests stored in the memory. The user will not be able to choose which tests to delete and which tests not to delete.

Go to the *Device* menu > *Device manager.*

In the *Device manager* click on *Delete the device memory*.



Once the memory has been deleted, the device must be switched off and on again for the new tests to be saved to the device memory.

4.5.3 SETTING UP THE DEVICE

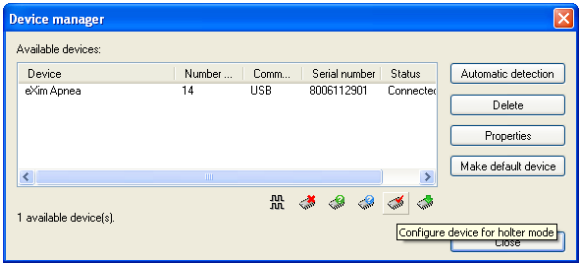
Before starting the test in holter mode, the device has to be prepared for the test. This basically consists in setting up the sampling frequencies of the channels in the Bitmed eXea system. If the user always performs the same type of test, the device only needs to be set up once.

By default, all the channels record at a sampling frequency of 100 Hz, but this can be changed depending on the sensors connected

to each channel.

Go to the *Device* menu > *Device manager.*

In *Device manager* click on *Set up the device for holter mode*.



The *Viewing options* will appear, as though you were going to perform a real-time test or download the device memory.

If you have created a montage with the channels you wish to acquire and their frequencies, you can use this. Otherwise, change the sampling frequencies of each channel as specified below.

Click on *Accept* when you are done. The software will set up the device and it will be ready to record in holter mode.

4.5.4 DOWNLOADING THE TEST

Once the test has been completed (see the detailed explanation on how to perform a test in holter mode in the device manual) it must be downloaded to the PC for review.

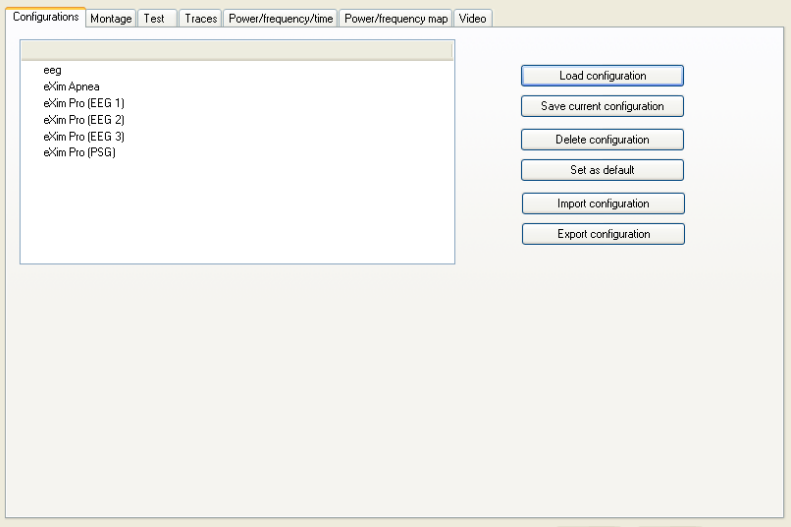
Have the database window open and choose the corresponding patient in the list.

Click on *Download memory*. The *Viewing options* dialog box will appear. Enter the set up options of the test in this box (sensors used during the test, filters, epoch duration, etc.).

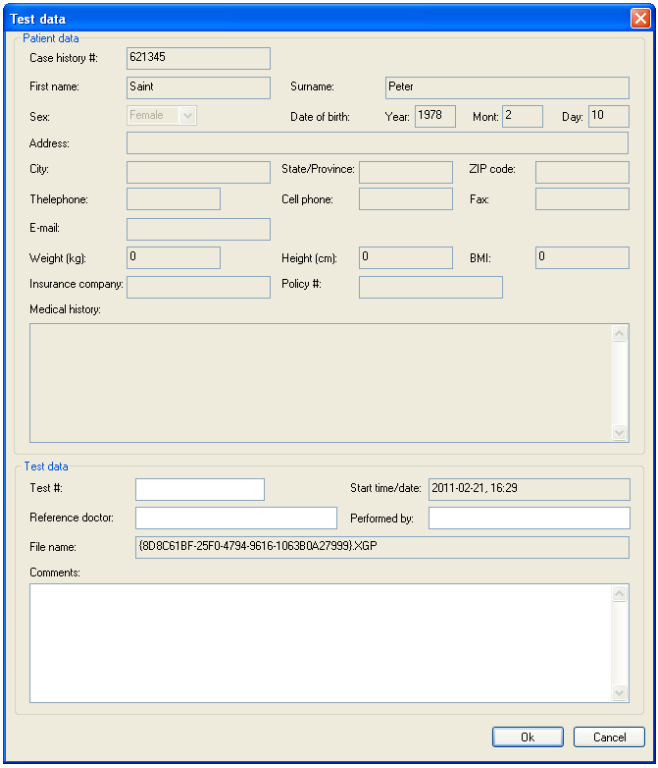
These data can be customized each time a new test is started in holter mode, but it is more convenient to save all the parameters under a *default configuration*, that can be then loaded directly or established by default for all the new tests to be performed. You can find more information on managing default configurations further

along in this manual.

To apply an existing configuration or settings other than the default settings to the test, choose the them from the list and click on *Read configuration.*



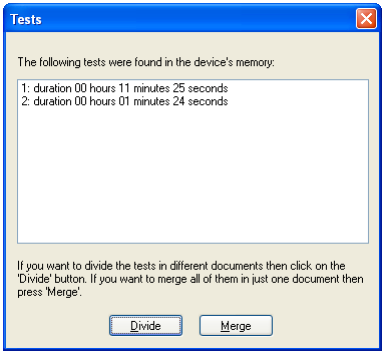
Enable the *Test* tab and click on *Test data.* A dialog will open for the user to enter the test data. These data appear in the report generated by the program and in the test epoch printouts. Click on *Accept* when you are done.



The transfer of memory data from the device to the computer will start. The progress bar that appears on the screen indicates the percentage of the procedure completed.

When downloading is complete, the program will indicate that the operation has finished.

If only one test has been performed, the test will open directly for review. If there is more than one test, the program will display a window with the list of all the tests and their duration and will ask if the user wishes to separate the tests into different documents or keep them in a single document, while annexing one recording after another.


Tests
The following tests were found in the device's memory:
1: duration 00 hours 11 minutes 25 seconds
2: duration 00 hours 01 minutes 24 seconds
If you want to divide the tests in different documents then click on the 'Divide' button. If you want to merge all of them in just one document then press 'Merge'.
Divide
Merge

4.6 REVIEWING THE TESTS

4.6.1 REVIEWING A TEST

Have the database window open and choose the corresponding patient in the list.

Choose the test you wish to open and click on *Review test* .

4.6.2 FULL SCREEN MODE

Use the full screen mode to maximize the available screen space to review the test. The Windows task bar, the title bar of the application and the toolbars will all disappear in this mode (display them by going to the *View* menu > *Toolbars and coupling windows*).

Go to *View* > *Full screen* to enter the full screen mode.

To exit the full screen mode, click on the *Close full screen* floating button or go to the *View* menu > *Full screen*.

4.6.3 DOUBLE WAVEFORM WINDOW

The waveform window can be divided into two parts during review. The two waveform windows can be set up with different time scales. In addition, each waveform can be displayed or hidden in either of the windows. Therefore, for example, in a sleep study the top window can be configured to view the fast channels and the bottom window to display the slow channels, each with a different time range.

The time scale used in the top window is shown in violet over the time scale used in the bottom window.

4.6.4 PLAYING THE TEST

Any of the tests can be played automatically at different speeds.

Place the cursor at the beginning of the part of the test that you wish to play. This can be at the very beginning or any other moment of the test.

Click on the *Start playing test* button on the play toolbar.

The test will start playing exactly as it was acquired. If you wish to double the playing speed, click on the *x2* button *(Increase the test playing speed*). If you wish to decrease the playing speed by half, click on the */2* button *(Decrease the test playing speed)*.

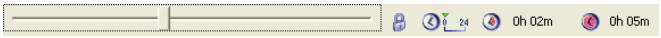
You can stop playing the test at any time by clicking on the *Pause playing test* button . You can start playing the test from the same point where it was stopped by clicking again on the *Start playing test.*

To stop playing the test, click on the *Stop playing test* button . The difference between this button and the pause button is that when play is resumed, it does so from the beginning of the epoch on the screen.

4.6.5 SCROLLING THROUGH THE TEST

Using the time bar

The time bar allows the user to scroll through the test quickly. Simply drag the scroll bar to move to another moment in the test. Scrolling will take place in the window that is active at the time (framed in yellow). The current time and the total duration of the test is shown to the right of the scroll bar.



Using the keypad

The following keys are used to scroll through the test:

Start: moves to the beginning of the test

End: moves to the end of the test

Page down: goes to the next epoch

Page up: goes to the previous epoch

Left arrow ← : goes back a short time in the epoch

Right arrow → : goes forward a short time in the epoch

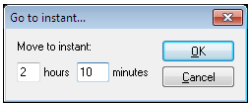
Forward half epoch

Use the *Advance a half epoch* button on the Viewing toolbar to advance a half epoch. This option is useful for a clear view of events that occur at the limit between two consecutive epochs.

Using the Go to instant option

Open the *Analysis* menu > *Go to instant*.

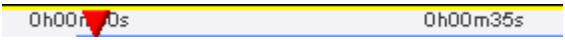
The user can specify the hour and minute of the test he wishes to go to in the box that appears.



Click on *Accept* for the test to automatically go to the indicated instant.

Using the browsing marks

If there is a place in the test of special interest that you wish to refer to in the future, a browsing mark can be inserted at that place from the *Analysis* menu > *Insert browsing mark*, or by pressing on the Ctrl+M key combination. The mark is shown as an upside down red triangle on the time scale.



To return to the same point again, simply go again to *Analysis* > *Browse to browsing mark* or press on the Ctrl+N key combination.

4.6.6 ADJUSTING TIME ON THE SCREEN

The time scale at the top of the waveform window shows the test time and the size of the epoch. The size of the epoch also appears on the status bar.

Adjust the time on the screen with keys + and - and icons .

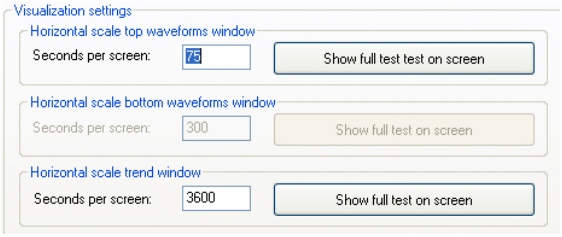
Use the + and – keys to multiply or divide the size of the epoch by two. This can also be done by using the toolbar icons and .

Specifying the number of seconds per epoch

Open the *Viewing options* window from the *Analysis* menu > *Viewing options*.

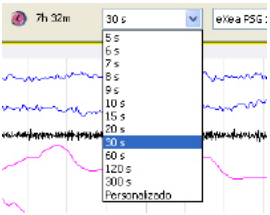
Enable the *Waveforms* tab. This tab has three text boxes that specify the visible time range in each window, one for the top waveform window, one for the bottom waveform window and one for the trends window. For each of these there is an associated button: *See complete test in one screen* to compress the entire test on a single screen.

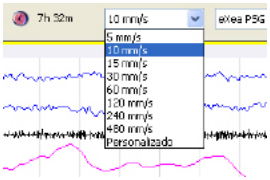
These adjustments can be applied separately to the top waveform window, the bottom waveform window or the trends window. However, the time range in the top waveform window cannot be longer than that of the bottom waveform window and the time range of the bottom waveform window cannot be longer than that of the trends window.



Using the Time toolbar

Specify the duration of the epochs in seconds or mm/s from the first list on the left of the Time toolbar. The values of this list will appear in seconds or mm/s, depending on the software settings. The screen must be previously calibrated for the mm/s scale to coincide with the real situation.





If you wish to toggle between seconds and mm/s:

Go to *Tools* > *Options*.

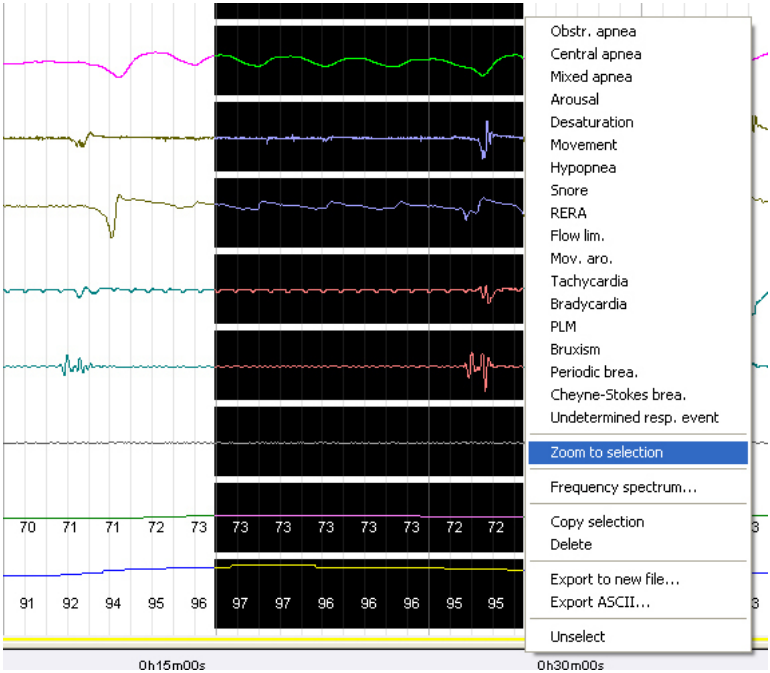
Enable the *General* tab.

Choose the desired option in the list of *Epoch units*: seconds or mm/s.

Zooming in on part of the test

Left click on any of the channels where you wish to start the enlargement.

Without releasing the left click, drag the mouse to the end of the part that you wish to enlarge.

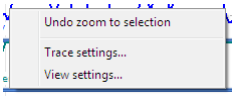


A contextual menu will appear. Select the *Zoom selection* option.

Undoing the zoom on an area of the test

To undo the zoom on an area of the test, right click on any of the waveforms.

Select *Undo zoom selection* in the menu that appears.



Modifying the time references

The software provides the user with two ways to show the time in the different views:

Reference of the time scale to the instant 00h:00m:00s: the time

line begins at instant 0.

Reference of the time scale to the time the test is performed: the time line begins at the instant the test performance is started.

Changing these time baselines does not affect the test performance time data.

Go to *Options* menu > *Viewing options* and enable the *Waveforms* tab.

In the *Time references* box choose *Reference of the time scale to the instant 00h:00m:00s* or *Reference of the time scale to the time the test is performed*, depending on which you prefer.

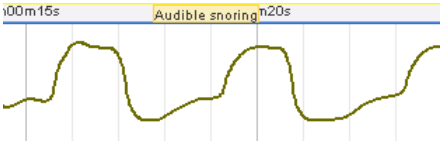
Click on *Accept* to apply the changes.

4.6.7 NOTES

The user can enter notes throughout the test for important observations. This option can be very useful during a real-time test if the technician wishes to take down visual observations of the patient (restless, moves, wakes up, etc.) or to take down changes in CPAP application, drug administration and so on. ALl the notes will appear later in the test report, along with the instant when they were entered.

The program enters a note automatically each time a real-time or holter recording is performed. A note is also inserted each time user events marker pulsing occurs.

These notes are shown on the time scale of the waveform window.



Entering a note

There are two different ways to enter notes:

Select *Enter note* in the *Analysis* menu.

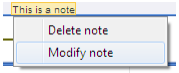
Press the *Insert* key on the keypad.

A box will appear for the user to enter the text of the note. The user can also choose one of the predefined notes that appear. If the test is being performed in real time, the note will appear overwritten at the instant it is being acquired. However, if a test that has already been acquired is being viewed, the note will appear overwritten at the instant corresponding to the center of the screen being viewed at that time.

Modifying a note

Right click on the note to be modified.

Select *Modify note* in the contextual menu that appears.

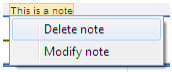


The *Enter note* window will appear. Modify the text and click on *Accept* to apply the changes.

Deleting a note

Right click on the note to be deleted.

Select *Delete note* in the contextual menu that appears.



Showing/hiding notes

Go to the *Analysis* menu > *Viewing options* or from the corresponding button of the side toolbar.

Enable the *Waveforms* tab.

Enable the *See notes* option to show the notes on the screen and disable the option to hide them.

Click on *Accept* to apply the changes.

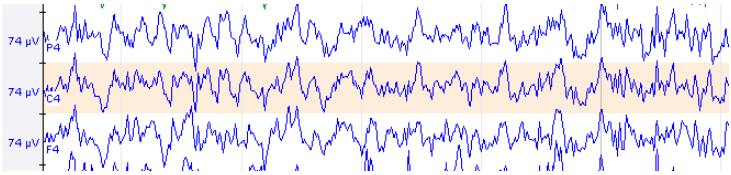
Modifying predefined notes

The default text provided by the program when entering notes can be completely customized to user preferences. This is done by editing the *notes.txt* text file in the application folder (default *X:/Program files/Bitmed/BitmedLab x.x*). Remember to enter one note per line.

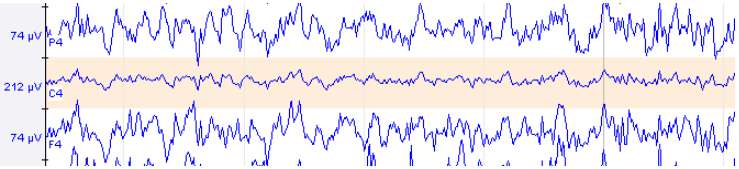
4.6.8 ADJUSTING WAVEFORM RANGES

Adjusting ranges with keys ↑ and ↓ or the mouse

Left double click on the waveforms that you wish to change the range of. The background of the channel will change color.



Use the ↑ and ↓ keys to increase or decrease the range of the selected waveforms.

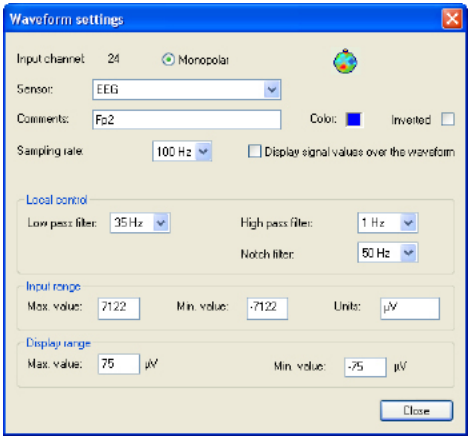


The amplitude of any channel may also be increased or decreased by clicking on it and then pressing the + and - keys, while holding the left mouse button.

Accurately adjust the amplitude of a channel (sleep disorders)

Right click on the waveform to be changed and select the *Channel properties* option.

The *Channel options* window will open. Change the values in the viewing range and enter the maximum and minimum values that you wish to see on screen for that channel.

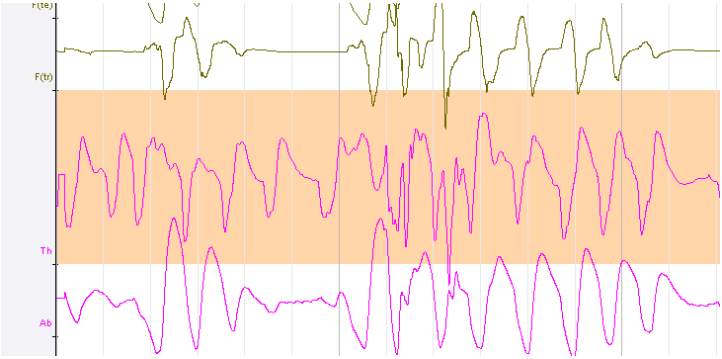


Click on *Close* when you are done.

4.6.9 ADJUSTING WAVEFORM SIZES

When the cursor passes over the separating lines of the waveforms, it changes to two arrows. This indicates the possibility of dragging the separation line to change the height of the waveform. Pull

the line up or down while left clicking to change the height of the waveform to the minimum or maximum height. This functionality can be enabled or disabled from the *Allow changes to the waveform size* option in the *Viewing* tab in the *Viewing options* window.



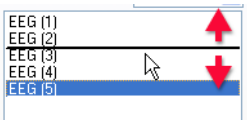
4.6.10 MODIFYING THE VIEWING ORDER OF THE WAVEFORMS

Go to the *Analysis* menu > *Viewing options* or from the corresponding button of the viewing toolbar.

Enable the Montage tab.

In the *Waveform window* list, select the waveform window where the changes to the channel viewing order will be made (top or bottom).

To change the order of a waveform, click on the waveform and without releasing the left click, drag it to the new position. Release the left click.



When you have finished adjusting the order of the waveforms, click on *Accept* to apply the changes to the test.

4.6.11 NAMING THE WAVEFORMS

Changing the waveform name display from the Viewing options window

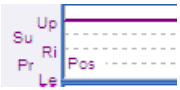
Open the *Viewing options* window from the *Viewing toolbar* button or from *Analysis* menu > *Viewing options*.

Enable the Waveforms tab.

Four different waveform name displays are available in the *Waveform description* list:

Detailed: this includes the channel number, long name of the associated sensor and its description.

Brief: this shows only the abbreviated name of the sensor or the name of the electrode if it is defined.



Off-channel: this is similar to the previous one but shows the title to the left of the waveform and hides the scale.

No description: this hides all the text on the waveforms.

When you are finished, click on *Accept* to apply the changes to the test.

Using the keypad to change the waveform name displays

The waveform name displays can also be changed by using the keypad. Use the "C" key to scroll through the four display options.

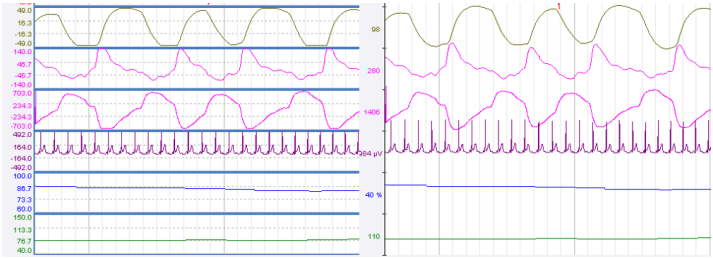
4.6.12 HIDING OR SHOWING SEPARATION BETWEEN WAVEFORMS

Open the *Viewing options* window from the *Viewing toolbar* button or from *Analysis* menu > *Viewing options*.

Enable the Waveforms tab

Enable or disable the *See channel separating bar* option.

Click on *Accept* to apply the changes.



4.6.13 ADDING AND DELETING WAVEFORMS

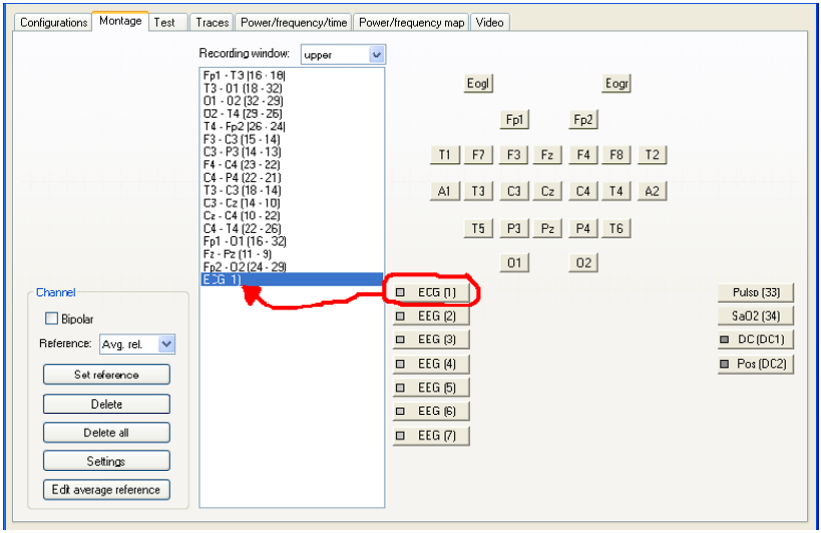
Adding waveforms

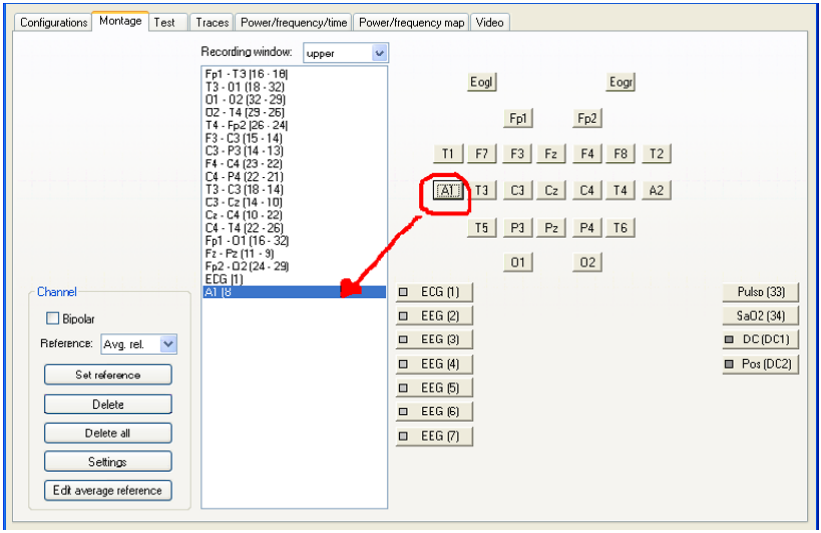
Go to the Analysis menu > Viewing options.

Enable the *Montage* tab.

Choose the top or bottom waveform window that you wish to set up from the *Waveform window* list.

All the inlet channels of the device appear on the right of the window (the channels available will depend on the type of device). Click on the ones you wish to add to the list of channels.





When all the desired channels have been added, click on *Accept* to close the window and apply the changes.

4.6.14 DELETING WAVEFORMS

Go to the Analysis menu > Viewing options.

Enable the *Montage* tab.

Choose the top or bottom waveform window that you wish to set up from the *Waveform window* list.

Choose the visible waveforms that you wish to delete from the waveform list.

Click on *Delete* and the waveform will disappear from the list of visible channels.

Click on *Accept* to close the window and apply the changes.

4.6.15 DELETING ALL THE WAVEFORMS

Go to the Analysis menu > Viewing options.

Enable the *Montage* tab.

Choose the top or bottom waveform window that you wish to set up from the *Waveform window* list.

Click on *Delete all* to delete all the waveforms at once.

Click on *Accept* to close the window and apply the changes.

4.6.16 SETTING UP THE SENSOR ASSOCIATED TO EACH INPUT CHANNEL

Before acquiring a new test or reviewing an existing test, the software must know which sensors/signals were connected to each of the input channels in the Bitmed recording device. When all these have been set up, the changes can be saved as a default configuration that can be used afterwards.

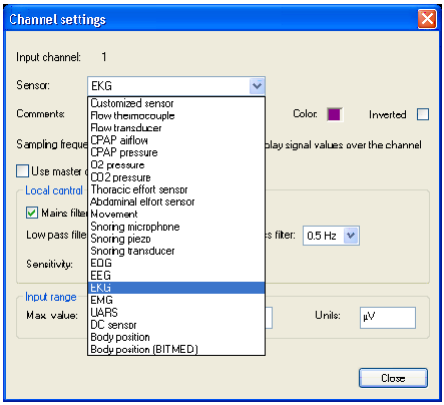
Go to *Analysis* menu > *Viewing options* and enable the *Montage* tab.

Assuming that the channel is already in the list of visible channels,

double click on it or select it and click on *Properties*.

The *Channel properties* window will open. In the *Signal type* list, select the sensor that has been connected to the corresponding channel of the device.

If the sensor you wish to connect to the device does not correspond to any of those that appear in the list of signal types, contact Sibel S.A. for instructions on how to use it.



Click on *Close* to close the window.

Click on *Accept* in the *Viewing options* window to apply the changes.

During the performance of the test, check that the sensor connected to each channel corresponds to the selected channel configuration.

4.6.17 CHANGING THE SOFTWARE FILTERS

The low pass and high pass filters applied to each channel can be changed from *Channel properties*, as seen in the previous section.

4.6.18 CREATING EEG/EOG DERIVATIONS

To create an EEG or EOG derivation, you will need two reference

channels (single pole). Some devices, such as Bitmed eXea PSG series 4 and 5 or Bitmed eXea Ultra have hardware reference channels. In other cases, you may want to convert differential channels (bipolar) into reference channels (single pole) by means of a bridge between channels (refer to the user's manual of the device for more information on this procedure). If so, the hardware has to know that the channel has been converted to a reference channel.

Setting up a differential channel as a reference channel

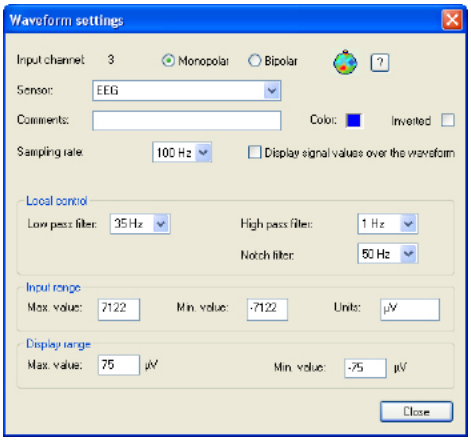
Go to the *Analysis* menu > *Viewing options*.

Enable the *Montage* tab.

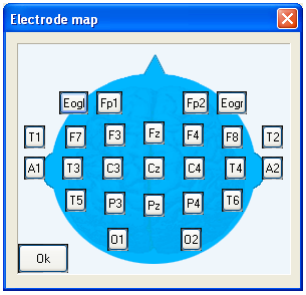
Assuming that the channel is already in the list of visible channels, double click on it or select it and click on *Properties*.

The *Channel properties* window will open. Choose the signal type (EEG or EOG) for the channel to display from the *Signal type* list.

Enable the option *Reference.*



You can enter the text regarding the position of the electrode in the *Additional description* text box by hand or click on the header icon, which will open the *Electrodes map*.



In the Electrodes map, click on the electrode connected to the channel that is being set up and click on *Accept.*

The name of the electrode will be added automatically to the *Additional description* text box in *Channel properties*.

Click on *Close* to close *Channel properties*.

Verify that the name of the channel has been changed in the list of visible waveforms of the *Montage* tab and the name of the electrode that has been connected to the channel appears in its place.

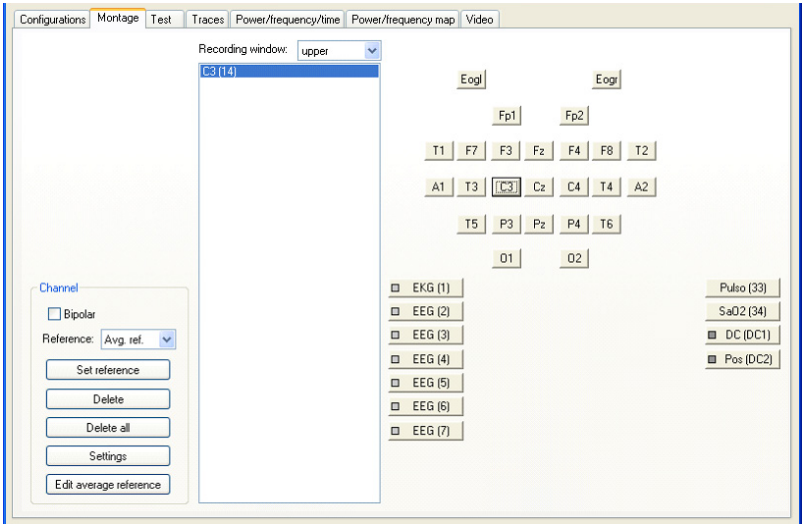
Creating a derivation by establishing a channel reference

Open the *Viewing options* window from the *Analysis* menu > *Viewing options*.

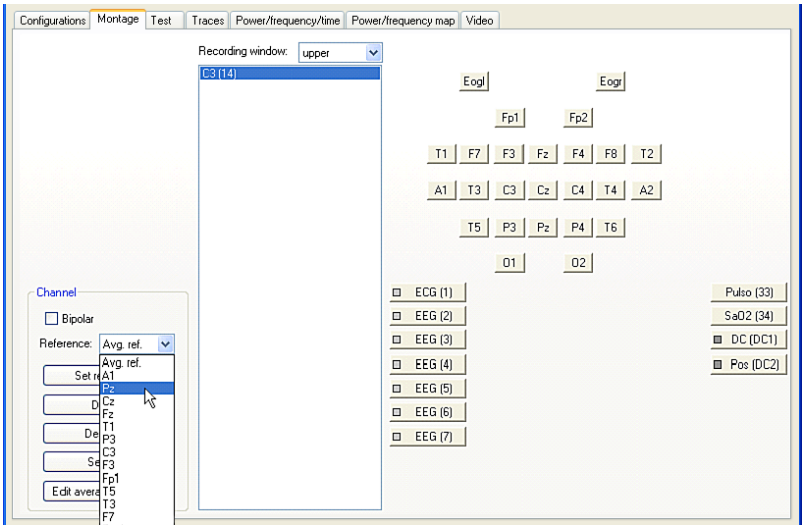
Enable the *Montage* tab.

Select the waveform window of the channel that you want to establish a channel for.

In the list of visible waveforms, choose the channel that you want to establish a reference for. Remember that the chosen channel must be a reference channel.

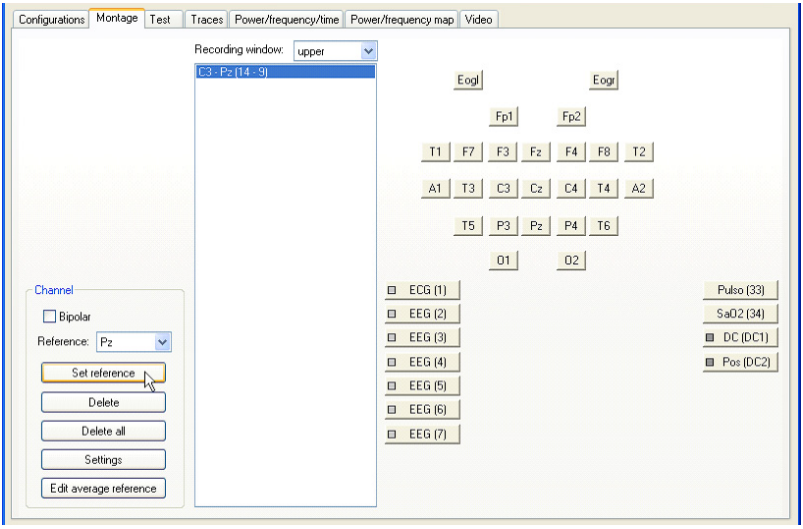


Display the *Reference* list and choose the reference that you wish to use for the channel. This can be any of the other reference electrodes or an averaged reference (setting up an averaged reference is explained further along).

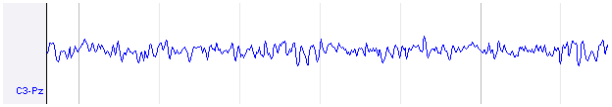


Click on *Set up reference*. The channel input in the list of visible

channels changes.



Click on *Accept* to see that a new channel has been created as a result of referencing one inlet channel to another.



Creating a derivation by selecting its two electrodes

This alternative method for creating derivations allows the user to create new derivations easily and quickly:

Open the *Viewing options* window from *Analysis* > *Viewing options*.

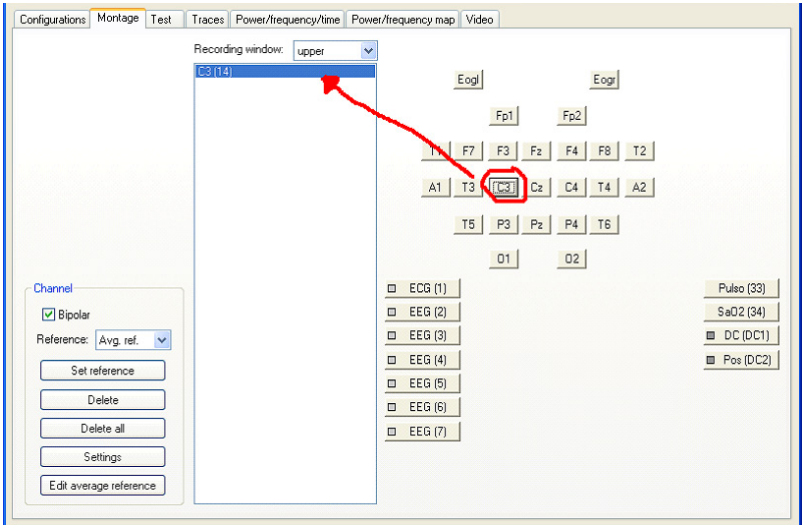
Enable the *Montage* tab.

Choose the waveform window where you wish to create the new derivation.

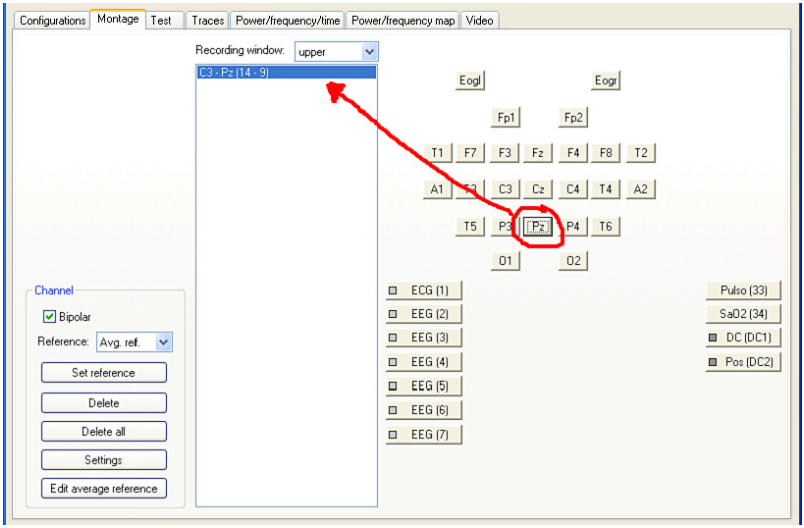
Enable the *Bipolar* box in the *Channel* panel.

On the right part of the window, click on the first electrode of the

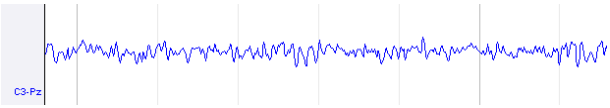
derivation.



Now choose the second electrode of the derivation. As a result, the inlet description in the list of visible channels will change.



Click on *Accept* to see that a new channel has been created as a result of referencing one inlet channel to another.



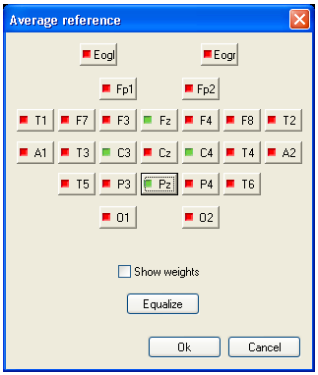
Editing the averaged reference

Go to the *Analysis* menu > *Viewing options*.

Enable the *Montage* tab.

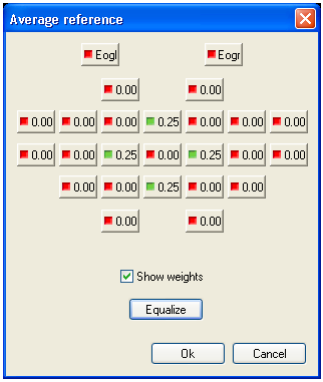
Click on *Edit averaged ref.*

A window will open from which to modify the averaged reference. The electrodes that comprise the averaged reference appear with a green mark, while those that are not used appear with a red mark.



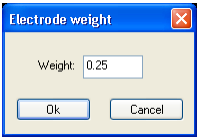
Select the electrodes that comprise the averaged reference by clicking on them and changing the color of the mark from red to green.

If the *Show weights* option is enabled, the name of each electrode will be replaced with its weight when the values of each electrode are averaged to generate the reference. Electrode weights goes from 0 to 1. The default weight of all the electrodes is 1.



If you wish to distribute the weight of the electrodes evenly, click on *Equalize*.

To change electrode weights manually, click on the electrode while the weights are being displayed and enter the new weight of the electrode in the *Edit electrode weight* window.



When you have finished editing the averaged reference, click on *Accept* to close the window.

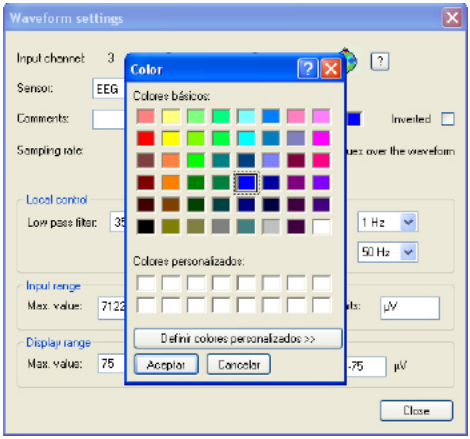
4.6.19 CHANGING THE SIGNAL WAVEFORM COLOR

Each type of sensor is given a different color by default, but the colors of each of the waveforms can be easily modified.

Right click on the waveform to be changed and select the *Channel properties* option in the contextual menu.

The *Channel properties* window will open. There is a *Color* box with the current color setting of the signal waveform.

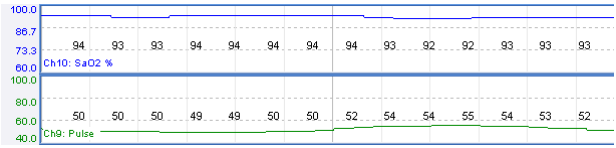
Click on the color box to open the color selection dialog and choose the new color for the signal waveform. Click on *Accept* when you are done.



Close *Channel properties* by clicking on *Close.*

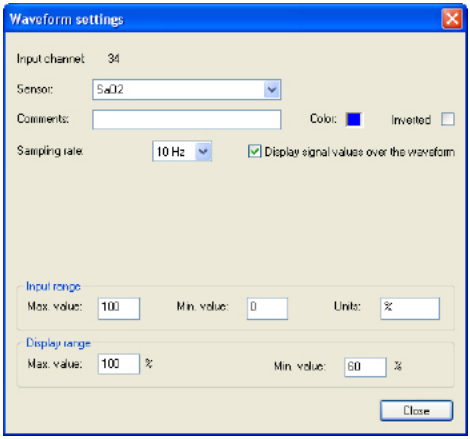
4.6.20 DISPLAYING THE WAVEFORM VALUES

If you wish, you can display the real values of the signals on the waveform at regular intervals.



Click on the right button of the channel over the waveform to be changed and select the *Channel properties* option in the contextual menu.

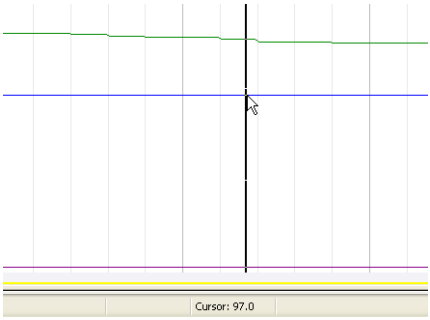
Enable the *Show values on channel* option.



Click on *Close* to close *Channel properties*.

4.6.21 NUMERICAL VALUES CURSOR

The numerical value cursor is a vertical line that the user can scroll freely across the screen. The status bar shows the value of the signal in the position and the channel that the cursor is on. To display it:



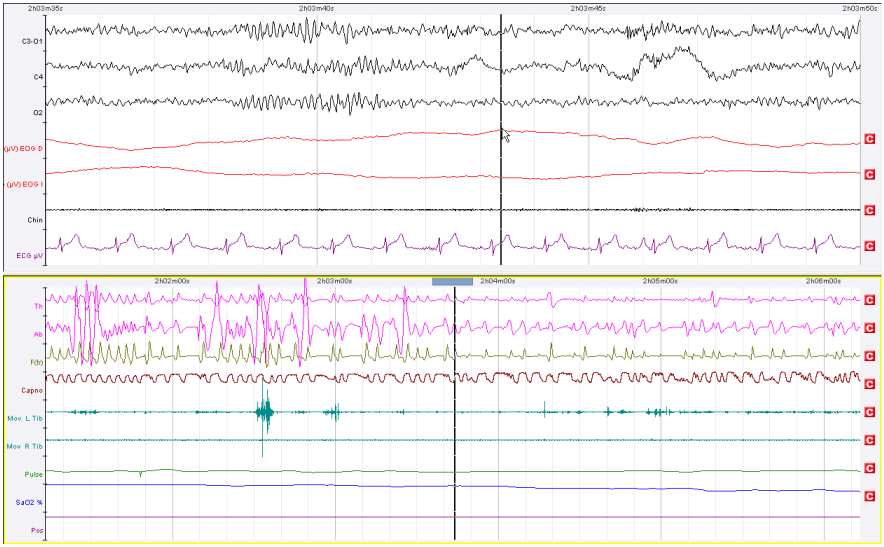
Go to the *Analysis* menu > *Viewing options*.

Enable the *Waveforms* tab.

Mark the box that corresponds to the *See numerical values cursor* option.

Click on *Accept* to apply the changes.

Once the bottom waveform window is visible, it also displays a cursor that is synchronized with the cursor in the top window, always so that it always marks the time instant of the top waveform window.



4.6.22 DEFAULT CONFIGURATIONS

A default configuration stores all the settings of a test under a descriptive name. This includes:

Channel settings: sensors, filters, gains, colors, descriptions, order on the screen, etc.

Screen settings: epoch duration, event mark viewing, real time display mode, event bar viewing, channel sizes, etc.

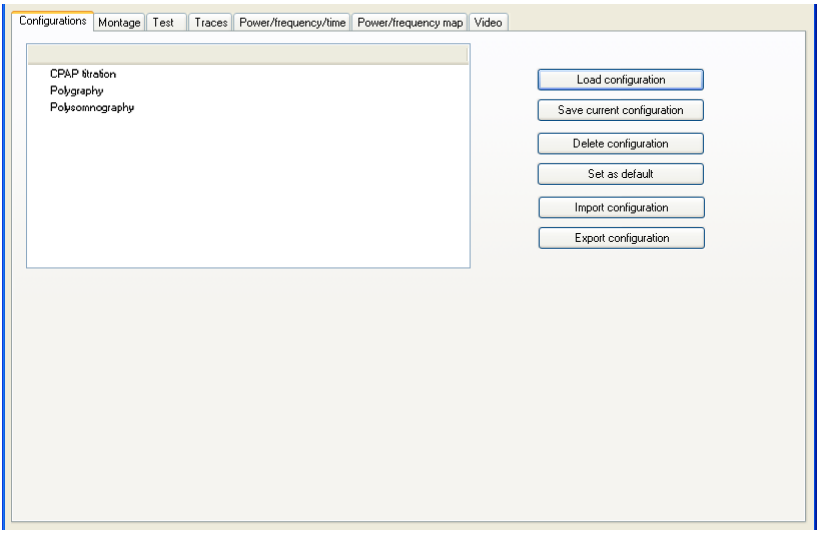
In general terms, all the parameters that can be set from the *Viewing options* window are stored in the default configuration.

The default configurations are saved with a name and can then be loaded and applied to the test at any time, whether on starting a real-time test, setting up the device for use in holter mode,

downloading a test to the device memory or during review.

In addition, if the same type of test is performed on a regular basis, a default configuration can be established for the software to apply it automatically to all new tests.

The default configurations are managed from the *Default configurations* tab in *Viewing options.* The default configuration applied to the test can also be changed from the montage bar.



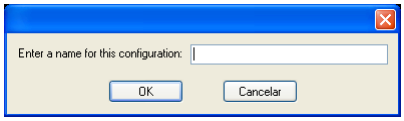
Saving a default configuration

Once the test has been set up to your liking, go to *Analysis* > *Viewing options*.

Enable *Default configurations.*

Click on *Save current configuration*.

The program will request a name for the default configuration. Enter the name and click on *Accept*. If there is already a configuration with the same name, the program will request confirmation to overwrite it.



Loading and Applying default configurations from Viewing options

Go to the *Analysis* menu > *Viewing options*.

Enable *Default configurations.*

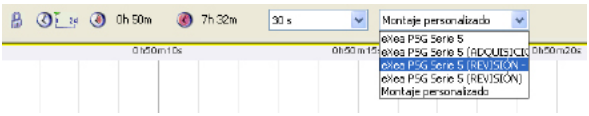
In the list of available configurations, choose the one you wish to apply.

Click on *Read configuration.*

Click on *Accept* to apply the changes.

Loading and applying default configurations from the Time toolbar

If you wish to quickly change the default configuration applied to the test, display the list of settings in the *Time toolbar*. Choose the new configuration and these will be applied instantly.



Establishing default settings for new tests

Go to the *Analysis* menu > *Viewing options*.

Enable *Default configurations.*

In the list of available configurations, choose the one you wish to establish as default.

Click on *Establish as default*.

The program will ask whether you wish to apply the configuration

to the active test.

Click on *Accept* to apply the changes.

Exporting and importing default configurations

The program allows the user to export a configuration to a file, so that they can be easily imported into another computer.

Go to the *Analysis* menu > *Viewing options*.

Enable *Default configurations.*

In the list of available configurations, choose the one you wish to export.

Click on *Export configuration*.

A dialog will appear to choose the name of the file that will store the default configuration and the folder to save it in.

The configuration will be saved in a file with extension *.xcp*

The procedure for importing a default configuration is similar:

Click on *Import configurations* in *Default configuration*.

A dialog will appear to choose the .xcp file corresponding to the default configuration that is to be imported.

The default configuration will be added to the list.

Deleting default configurations

Go to the *Analysis* menu > *Viewing options*.

Enable *Default configurations.*

In the list of default configurations, choose the one you wish to delete.

Click on *Delete configuration*.

4.6.23 AUTOMATIC ANALYSIS OF SLEEP STAGES

The program displays the sleep stage information in two different ways: with the hypnogram

or by means of a bar where the sleep stages are distinguished by a color code:

Artifacts: dark green

Waking: magenta

Stage 1: blue

Stage 2: light green

Stage 3: yellow

REM: black

Depending on the time setting of the trends window, the hypnogram or the stage bar will display the stage corresponding to the current epoch, the trends behind and ahead of the current epoch, the sleep structure of the entire night, etc.

The template of the polysomnography report also shows the compete hynogram of the entire night.

Performing an automatic analysis is the sleep stages

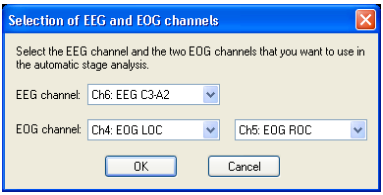
	The automatic analysis of the sleep stages is only available if the corresponding license has been purchased.

	The results provided by the Automatic Analysis of Sleep Stages should not be used as the sole criterion for medical diagnosis or patient treatment. The results must be supervised and reviewed by medical personnel with adequate training.

Choose the *Automatic stage analysis* option in the *Analysis* menu.

The program will ask you to confirm deletion of all the stages currently marked.

It will then request the channels to be used for the analysis. It will be necessary to have an EEG signal and two EOG signals available. Click on *Accept* to start the analysis.


Selection of EEG and EOG channels
Select the EEG channel and the two EOG channels that you want to use in the automatic stage analysis.
EEG channel:
Ch6: EEG C3-A2
EOG channel:
Ch4: EOG LOC
Ch5: EOG ROC
OK
Cancel

Manual marking of sleep stages

BitmedLab has two different ways of marking sleep stages manually.

First stage marking method:

In *Tools* > *Options*, enable the *General* tab and make sure the *Advance epoch when stage is entered* is disabled. Close the window.

Place the cursor at the beginning of the test.

Enter the stage corresponding to the first epoch. To do so, use the corresponding button in the *sleep toolbar* or the key associated with the stage. The software will introduce a mark from the beginning of the test to the end.

Use the PgDn key to review all the epochs until the beginning of the next sleep stage and mark it. The new mark will go from the

beginning of the current epoch to the end of the test.

Repeat the point above until you reach the end of the test.

Second stage marking method:

In *Tools* > *Options*, enable the *General* tab and make sure the *Advance epoch when stage is entered* is enabled. Close the window.

Place the cursor at the beginning of the test.

Enter the stage corresponding to the first epoch. To do so, use the corresponding button in the sleep toolbar or the key associated with the stage. The software will introduce a mark for that epoch and advance automatically to the second epoch.

Enter the sleep stage corresponding to the epoch on the screen. The software will automatically go to the next epoch.

Repeat the point above until you reach the end of the test.

Keys associated to each of the stages

Each sleep stage has an associated default key to enable stage marking with the keypad. The default keys are as follows:

Artifacts: A

Waking: V

REM: R

Stage 1: 1

Stage 2: 2

Stage 3: 3

The associated keys can be changed by going to *Tools* > *Options* > *Custom keys.*

You can also check the hoykeys in Annex 3 of this manual.

4.6.24 EVENT TYPES

BitmedLab defines a series of event types that the user can mark in the tests. For user convenience, BitmedLab limit the available event types according to the group of event types that are enabled at a given moment. There are three groups of event types (*simple, intermediate and advanced*), each of which enables certain types of events, as seen in detail in the table below:

	Simple	Intermediate	Advanced
Obstructive apnea	❍	❍	❍
Central apnea	❍	❍	❍
Mixed apnea	❍	❍	❍
Hypopnea	❍	❍	❍
Desaturation	❍	❍	❍
Snoring	❍	❍	❍
Flow limitation	❍	❍	❍
Limb movement		❍	❍
PLM		❍	❍
Regular breathing		❍	❍
Cheyne-Stokes breathing		❍	❍
Undetermined breathing event		❍	❍
Arousal			❍
Movement arousal			❍
RERA			❍
Tachycardia			❍
Bradycardia			❍
Bruxism			❍

Select a group of event types, depending on the type of test to be performed. For example, the *simple* type may be enough for a screening test, while the *advanced* type may be the proper option

for a cardiorespiratory polygraph.

Only one group of event types can be enabled at the same time in the program. In other words, if the *simple* group of event types is enabled and a test is opened with tachycardias marked, the latter will simply not appear. However, if the group is changed to *advanced*, the tachycardias will be seen perfectly.

Take the following steps to change the group of event types:

Go to the *Tools* menu > *Options.*

Choose the *Event types* tab.

Choose the group you wish to use from the list of *Group of event types*.

Click on *Accept* to apply the changes.

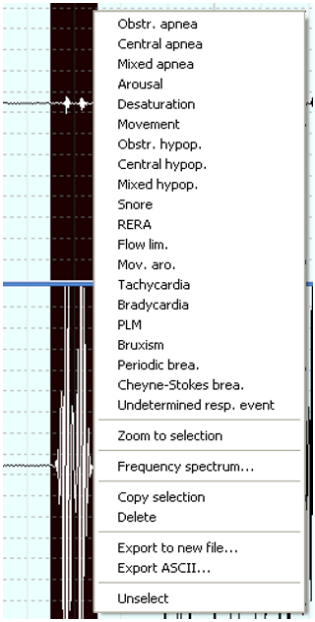
4.6.25 MANUAL MARKING OF SLEEP EVENTS

Marking events with the mouse

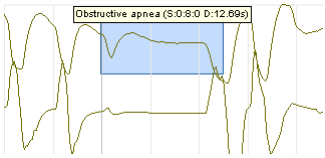
Click on the point where you wish to start the event.

Drag the mouse to mark the duration of the event. The duration of the current selection will appear in the status bar, in seconds. If you have clicked on an air flow or breathing effort waveform, the desaturation associated with the selection and the signal variation will also be shown. These data are useful for marking apneas and hypopneas.

When the selection has been completed, a contextual menu will appear with all the event types. Choose the one you wish to mark.



The event mark will appear. The mark can appear over one or more waveforms, depending on the property settings of the event type. If the trends window is open, a mark will also appear on the corresponding event type bar and the length will depend on the duration of the event. Finally, the number of event occurrences will increase by one.



Marking events with the keypad

Press the key associated with the event. The program will insert a mark starting at the beginning of the epoch on the screen, with a specific duration for this type of event.

Refer to the *Customized keys* tab of the *Settings* (*Tools* > *Options*) window for the key associated to each type of event.

You can also check the hoykeys in Annex 3 of this manual.

Marking event with the mouse and the keypad

Press on the key associated with the event that you wish to mark. The cursor changes to an arrow with the sign +.

Do not release the key and select the part of the test where you want to mark the event.

Release the key to mark the event.

Use the event marking toolbar

Choose the type of event that you wish to mark.

The cursor changes to an arrow with the sign +. Unless you click again on the event type icon, all the events that are marked will be of the same type.

Do not release the key and select the part of the test where you want to mark the event.

Release the key to mark the event.

4.6.26 AUTOMATIC ANALYSIS OF SLEEP EVENTS

	The automatic analysis of the sleep events is only available if the corresponding license has been purchased.

	The results provided by the Automatic Analysis of Sleep Stages should not be used as the sole criterion for medical diagnosis or patient treatment. The results must be supervised and reviewed by medical personnel with adequate training.

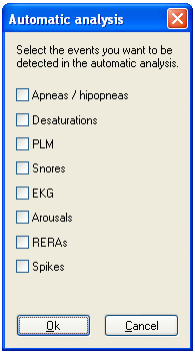
The program has an option that analyzes the test in order to detect and classify events: apneas, hypopneas, desaturation, PLM and limb movement, snoring, cardiac event (tachycardias and bradycardias), arousals and RERAs.

	The automatic analysis of events deletes all events marked previously in the test.

Take the following steps to perform an automatic analysis of sleep event:

Go to *Analysis* > *Automatic analysis of events*.

A window appears where you can select the type of events that you wish the program to detect. Click on *Accept* when you have made the selection.



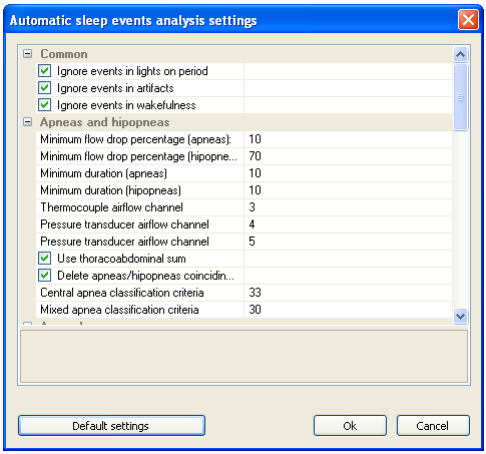
BitmedLab will warn you that all the events marked in the test will be lost. Confirm that you wish to continue.

The program will begin the analysis. The events detected will be

marked on the waveforms and in the event bars of the trends window.

4.6.27 MODIFYING THE OPTIONS FOR AUTOMATIC ANALYSIS OF SLEEP EVENTS

Go to the *Analysis* menu > *Options automatic analysis of events.*



Make the desired changes in the criteria for automatic analysis of events. An explanation of each of these parameters is shown when you click on the parameter. To return to the program default values, click on *Reset default parameters*.

Click on *Accept* to apply the changes.

4.6.28 WORKING WITH EVENTS

Modifying the default duration for events inserted with the keypad

Open the window *Tools* > *Options* > *Event types*.

Choose the event type you wish to customize and click on *Properties.*

Enter the desired duration with all the occurrences of the event entered with the keypad in the text box *Default duration of events entered with the keypad*.

Click on *Accept*.

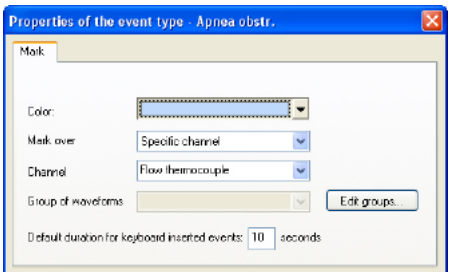
Close the *Event types* window.

Changing the color of the event marks

Open the window *Tools* > *Options* > *Event types*.

Choose the event type you wish to customize and click on *Properties.*

Click on the *Color* section and choose the desired color for the mark.



Click on *Accept* to apply the changes.

Hiding/showing the event marks on the waveforms

The events are marked with a color rectangle over the signal waveform. The mark also includes the event type, the time instant of the start of the event and its duration. These marks can be shown or hidden by the user.

Open *Viewing options* from the *Analysis* menu.

Enable the *Waveforms* tab.

To hide the marks, disable the option *See event marks on waveform*. To show the marks, enable the option *See event marks on waveform.*

Click on *Accept* to close *Viewing options* and apply the changes.

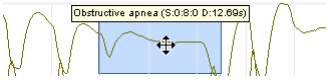
Hiding/showing the trends window

The trend window displays a bar for each type of event. The occurrence of each event is marked with a color rectangle on this bar. The number of occurrences of each event type appears next to each bar.

These bars are normally used to get a general idea at a glance of the trend of events over a long epoch of the test or the complete test. The trends window can be shown or hidden by clicking on the button of the *Viewing* bar or by clicking on the *See* > *Trends* menu.

Moving events

Place the cursor over the event to be moved. The cursor changes as shown in the illustration.

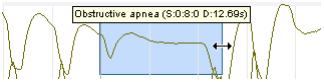


Click on the event and drag it while left clicking.

Release the left click when the event mark is in the desired position.

Changing event duration

Place the cursor over the left or right end of the event. The cursor changes as shown in the illustration.



Click and move the cursor to the left or right, while maintaining the left click.

Release the left click when the event mark is in the desired position.

Changing event types

Place the cursor over the event you wish to change and right click. A menu will appear with all the event types defined in the

application.

Choose the type of event to assign to the event.

Deleting events with the mouse

Press the *Control* key. The cursor changes to an arrow with the sign -.

Do not release the *Control* key and click on the event to be deleted.

Deleting events from the event mark

Place the cursor over the event you wish to delete and right click.

Choose the *Delete event* option in the contextual menu.

Deleting all the test events

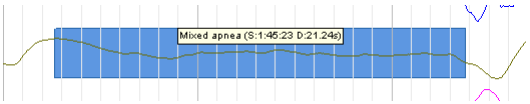
Choose the *Delete all events* option in the *Analysis* menu.

Confirm that you wish to delete all the test events.

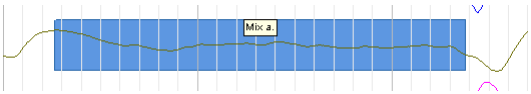
Changing the way the event marks appear on the screen

The event marks on the channel waveforms can be viewed in different ways:

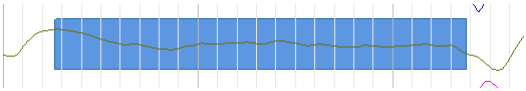
Detailed: a text appears on the mark that includes the event type, the initial instant and its duration.



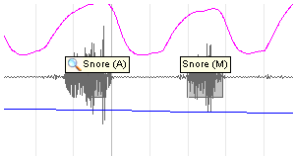
Brief: a text appears on the event mark only with the short name of the event type.



No description: no text appears. The event type is distinguishable only by the color of the mark.



Events inserted manually show the mark *(M)*, while events detected by automatic analysis show the mark *(A)*.



Toggle between the three views by using the "E" key or from *Viewing options*:

Open the *Viewing options* window from the *Analysis* menu > *Viewing options*.

Enable the *Waveforms* tab.

Choose the option you wish to use in *Event mark descriptions*.

Click on *Accept* to close the window and apply the changes.

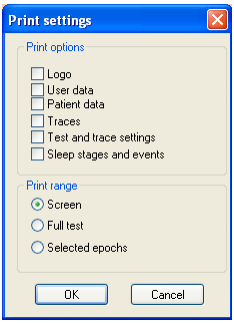
4.6.29 PRINTING

BitmedLab allows the user to print the stage being viewed on the screen, a selection of several epochs (consecutive or not) or the complete test.

Printing the on-screen epoch, the entire epoch or a selection of epochs

Browse to the epoch you wish to print and go to *File* > *Print.*

Choose the printed items to include in the dialog. For example, a header with user data and/or logo can be added. These options are saved each time printing is done.



Choose the printing range and click on *Accept*.

Direct printing

The epoch on the screen can be printed directly by simply clicking on *Direct printing* in the *Standard toolbar*. The epoch will be printed with the last settings used to print from *File* > *Print.*

Choosing epochs for future printing

While reviewing the test, a series of epochs can be selected to be printed at the same time.

Choose the epoch on the screen by clicking on *Select for printing* . The epoch is selected and distinguished from unselected epochs by a purple mark in the time reference area.

When you have finished choosing the epochs, go to *File* > *Print* and when the *Printing options* window appears, choose *Selected epochs* in the *Printing range* section.

Preliminary printing view

Go to *File* > *Preliminary presentation*.

Choose the items you wish to include in the preliminary view. You can also choose this window if you wish to preview the complete test, only the epoch being viewed on the screen or the epochs selected for printing. The epoch being viewed on the screen can be printed from the preliminary presentation.

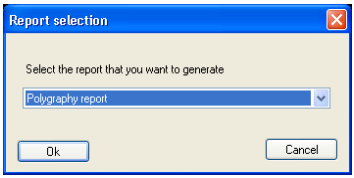
4.7 GENERATING REPORTS

4.7.1 GENERATING A REPORT

To generate a report from the database:

Choose the patient and the test for that you wish to generate the report for. Click on *See report* .

In the window, choose the report template to be used. Any new template generated will be added automatically to this list. If a report has already been associated with the test, it will open automatically; otherwise a new report will be generated, depending on the template that is selected.



To generate a report when the test is open on the screen:

Choose *Report* in the *See* menu. You can also use the button.

In the window, choose the report template to be used. Any new template generated will be added automatically to this list. If a report has already been associated with the test, it will open automatically; otherwise a new report will be generated, depending on the template that is selected.

For the calculation of the hypnogram and sleep statistics in a polysomnograph report to be made correctly, the user must previously analyze the sleep stages in the test and mark the status of the lights (off/on). Likewise, for all event information to appear correctly, the user must analyze it, either manually or automatically. If the stages are not defined, the analysis module differentiates the wake/sleep states according to the status of the lights.

If the test is edited after generating the report, the report will have to be generated again for the changes to appear.

4.7.2 PRINTING A REPORT

With the report open and activated on the screen, go to *File* > *Print.*

Choose the printer, printer properties, printing interval and number of copies.

Click on *Accept* to start printing.

4.7.3 SAVING A REPORT

Go to *File* > *Save.*

In *Save as*, enter the name of the report file, choose a folder to save it in and click on *Save*.

4.7.4 CHOOSING THE REPORT EDITOR

By default, the report will appear in a window in BitmedLab. If you wish, BitmedLab can open the report automatically in MS Word, which provides much better editing possibilities.

Take the following steps to change the report editor:

Go to the *Tools* menu > *Options.*

Enable the *Edit reports in MS Word* in the *General* tab.

Click on *Accept* to close the window and save the changes.

4.7.5 GENERATING AND MODIFYING REPORT TEMPLATES

The program is provided with several different report templates, designed for different types of tests. However, the user can generate new templates or customize the existing templates to adjust them to his needs.

The report templates are in the *Templates* folder of the *BitmedLab* folder (e.g.: C:/Program Files/Bitmed/BitmedLab 1.0/Templates).

The report templates are in RTF format. RTF is a universal file type for text formatting. The WordPad program, supplied with Windows or MS Word, two common programs, can work with this type of file.

All the templates saved in this folder will appear as templates that can be selected in the *Select report type* window. All that is required is to create a new template and save it in the *Templates* folder, where it will be available to generate a new report.

The report templates are based on the use of a series of labels that are later interpreted by the software to generate the reports.

For example, if a line in the template is:

Name: #name_pat#

the program will replace the #name_pat# label with the real name of the patient so the report shows:

Name: Nuria Pino Torres

If, on the contrary, the template has:

Total recording time: #TRT# min

the generated report will replace the #TRT# label with the total recording time:

Total recording time: 182 min

Any of the report templates supplied by default with the program can be opened in your usual text processor to verify its appearance.

Refer to the CD supplied with the software to familiarize yourself with the complete list of available labels to customize your reports.

Briefly, the steps to create a report template are as follows:

Open a word processor, such as Windows Write or MS Word.

Create a new document or edit any of the report templates in the *Templates* folder.

Customize the report. You can use, tables, text formatting (bold, various fonts, colors), insert images, etc. The text entered will appear the same in the report, while the labels with the #name_label# format will be automatically replaced with a value calculated by the program.

When you have finishes, save the file with the .RTF extension in the *Templates* folder.

From now on, the new template will appear in the list of available templates for the generation of reports.

5. ACQUIRING DIGITAL VIDEO

XGPVision is an optional module that allows the user to acquire synchronized digital video and audio in sleep studies.

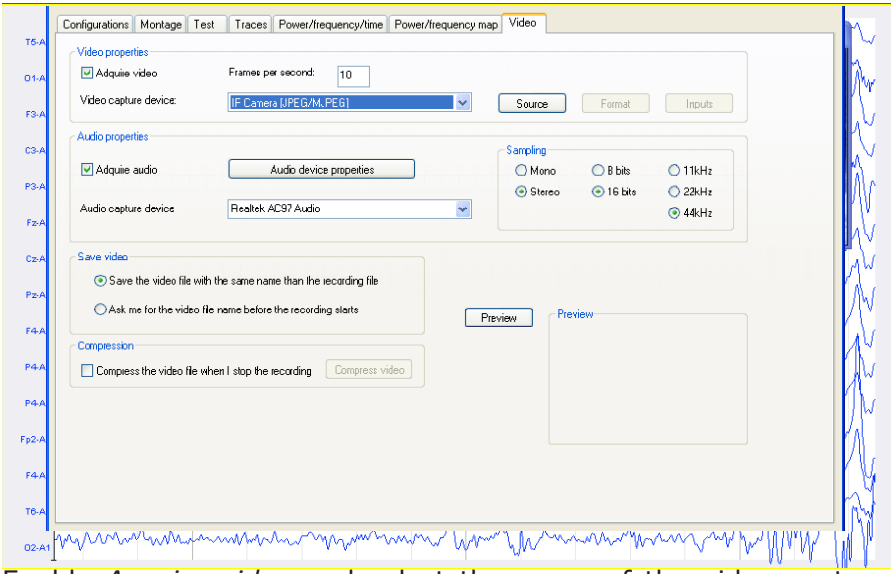
The audio and video are stored in a file different than that of the test file, in the same folder and with the same name, but with an .AVI extension. The video acquisition process is a demanding process for the computer, so video compression during capture is minimum. This generates large files (these can occupy several gigabytes) and they will need to be compressed after acquisition in order to be saved alongside the test. Video compression used an MPEG4 standard compressor that significantly reduces the size of the file. Audio compression uses a standard MP3. Compression significantly reduces the size of the file without affecting the quality.

XGPVision is completely integrated into BitmedLab and is very easy to use.

The functions described throughout this chapter are only available if you have purchased the XGPVision license.

5.1 ACQUIRING VIDEO DURING PERFORMANCE OF REAL-TIME TESTS

Start recording a new test in real time. When you are in *Viewing options* select *Video.*



Enable *Acquire video* and select the name of the video capture card from the list of *Video capture devices*. This list includes all the devices installed in the system capable of capturing video.

If you also wish to acquire audio, enable *Acquire audio*. As in the point above, select the audio device from the corresponding list.

Enable the *Ask me for the file name before starting recording* option if you want the program to request a name for the file that will store the video at the beginning of the test recording. If not, the video file will have the same name as the recording, but with the extension .AVI, and it will be saved in the same folder (we recommend this option).

Use *Preview* to preview the video source currently selected in *Previewing.*

Click on *Accept* to start the test and video capture.

A video viewing window will appear on the top right of the screen. The video is acquired at the same time as the signal data.

Once video acquisition has started, it can be paused and resumed at any time, which will also pause and resume the test recording. To do so, click on *Pause/resume direct communication*. Remember

that when the recording is paused, you can move freely through the test acquired up to that time, although the video will not synchronize with the time instant that is being viewed in the waveform window.

If, on the other hand, you stop the recording using *Stop direct communication*, you will not be able to add any more data to the test, but the video will synchronize with the time instant indicated by the waveform window.

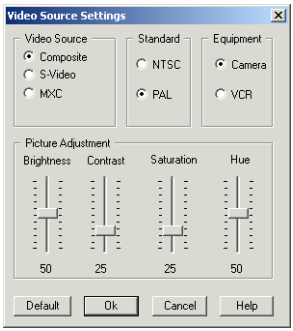
5.2 MODIFYING THE CAPTURE PROPERTIES

The audio and video capture properties can be changed from the Video tab in Viewing options.

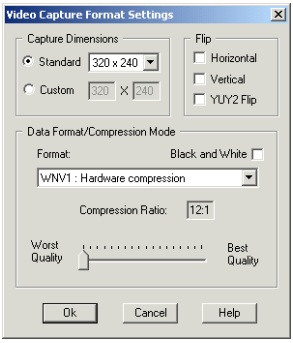
The capture properties can only be changed before starting the test.

Frames per second: the number of video frames that will be captured per second. Remember that a high rate per second will generate a much larger file, which may reach several gigabytes in long tests. For example, a test with 9 hours of compressed video at a rate of 5 frames/second occupies approximately 600 Megabytes.

Controls: these are used to change the capture properties of the card (brightness, contrast, saturation, etc.). Select the input source and the input signal type (camera, video). The available properties will depend on the model of the capture card in the system, and some of the options mentioned may be in another menu. Normally, the values needed are *Composite video* and *PAL system.*



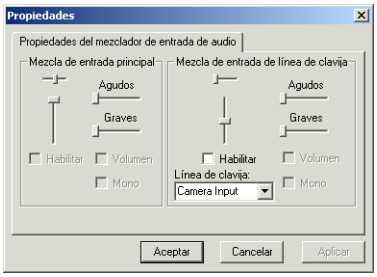
Format: this establishes the size of the capture window, the format of the images to be recorded, etc. If you have a Winnov Videum 1000 Plus capture card, we recommend using the Hardware compression format with a window size of 320x240 and selecting the desired compression quality. If you do not have a Winnov Videum 1000 Plus card, possible settings could be a similar window size but an image format of 24-bit RGB.



Inputs: this button is only available in certain card models (those with several inputs for video signals). A dialog appears for the user to select the input that the video source is connected to.

Video capture device: a list of the devices installed in the system capable of capturing video. Select the video capture card.

Audio device properties: this shows a new dialog where the user can select the input line from which to perform audio capture (camera Input, line Input, etc.). These options will vary depending on the sound card model or the video capture card, if the latter has an option for capturing audio.



Audio capture device: a list of the devices installed in the system capable of capturing audio. Choose the device that you wish to use in the tests.

Sampling: several audio recording features can be chosen in this block. Recording in stereo or mono, 8 or 16-bit coding (the higher the bit coding, the better the sound will be but this will also increase the space occupied by the file in the hard disk). You can also choose the capture sampling frequency, 11, 22 or 44 KHz. The higher the frequency, the larger the resulting file will be.

5.3 REVIEWING THE TEST

When the video recording of a test has been completed or a test with video is opened, the video window will be on the top right of the main window of the program.

The window can be hidden by clicking on the X and shown again from *See* > *Video*.

If the numerical data cursor is enabled, you can verify whether the video window is displaying the frame that corresponds to the time instant on which the cursor is placed.

If the cursor is not enabled, the video window will display the frame corresponding to the left end of the waveform window or the position of the pointer if a selection is being performed on the test.

The video will play automatically when you enable the play test function at the selected speed.

If any part of the test is deleted, the corresponding video will not be deleted, so it will cease to be synchronized with the biomedical signals.

5.4 COMPRESSING THE VIDEO FILE AUTOMATICALLY AFTER COMPLETING THE TEST

We recommend compressing the video file to significantly reduce its size. If you want the program to compress the video automatically once the test has been completed, choose the *Compress video after completing the test* option in the *Video* tab of *Viewing options.* Nonetheless, the program will request confirmation before performing the procedure, since the procedure is quite time-consuming for long tests.

5.5 COMPRESSING THE FILE AT ANY TIME

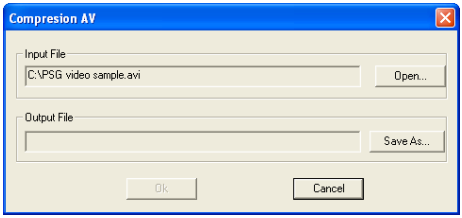
Open the test that you wish to compress the video of.

Open the *Viewing options* window from *Analysis* > *Viewing options*.

Enable the *Video* tab.

Start the video compressor by clicking on *Compress video now.*

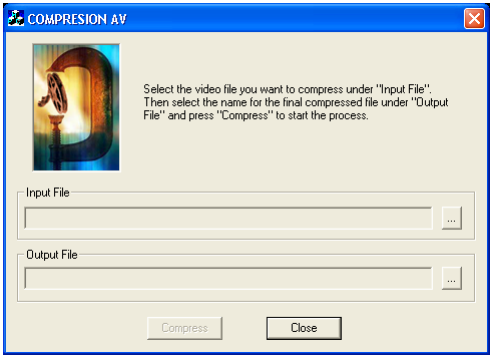
The *AV compression* dialog will open where you can choose the file to compress (the default file is the one associated with the active test) and the name of the compressed file. Click on *Accept* to start compression.



5.6 COMPRESSING A VIDEO FILE USING THE COMPRESORAV TOOL

The BitmedLab software product line includes the installation of a tool called Compresor AV that can be used to compress video files without needing to start any of the software modules (SleepLab, SleepLab Pro).

In the Windows *Start* menu, go to *All programs* > *BitmedLab* and open *Compresor AV*.


COMPRESION AV
Select the video file you want to compress under "Input File". Then select the name for the final compressed file under "Output File" and press "Compress" to start the process.
Input File
Output File
Compress
Close

Choose the video file to compress in *Input file*.

Choose the name for the compressed video file in *Output file*. You can choose the same file if you wish.

Click on *Compress* to start compression.

5.7 CHANGING THE VIDEO FILE ASSOCIATED WITH A TEST

This option only appears once test acquisition has been completed and allows the user to associate a video file other than the original

one. This is useful when the test file is moved from one folder to another or to another computer and the location of the video file does not coincide with the original.

Open *Viewing options* from *Analysis* > *Viewing options*.

Enable the *Video* tab.

Click on *Video file associated with the test* to choose the video file you wish to associate with the test.

Click on *Accept* to apply the changes.

6. FREQUENTIAL ANALYSIS TOOLS

The optional frequential analysis module provides the user with two working tools based on Fourier Fast Transform (FFT): the frequency spectrum graph (also known as spectral density) and the power/frequency/time graph.

The functions describe throughout this chapter are only available if you have purchased the frequential analysis license.

6.1 FREQUENCY SPECTRUM GRAPH

6.1.1 DISPLAYING THE FREQUENCY SPECTRUM GRAPH

The frequency spectrum graph shows the frequency contents of the selection in a given channel.

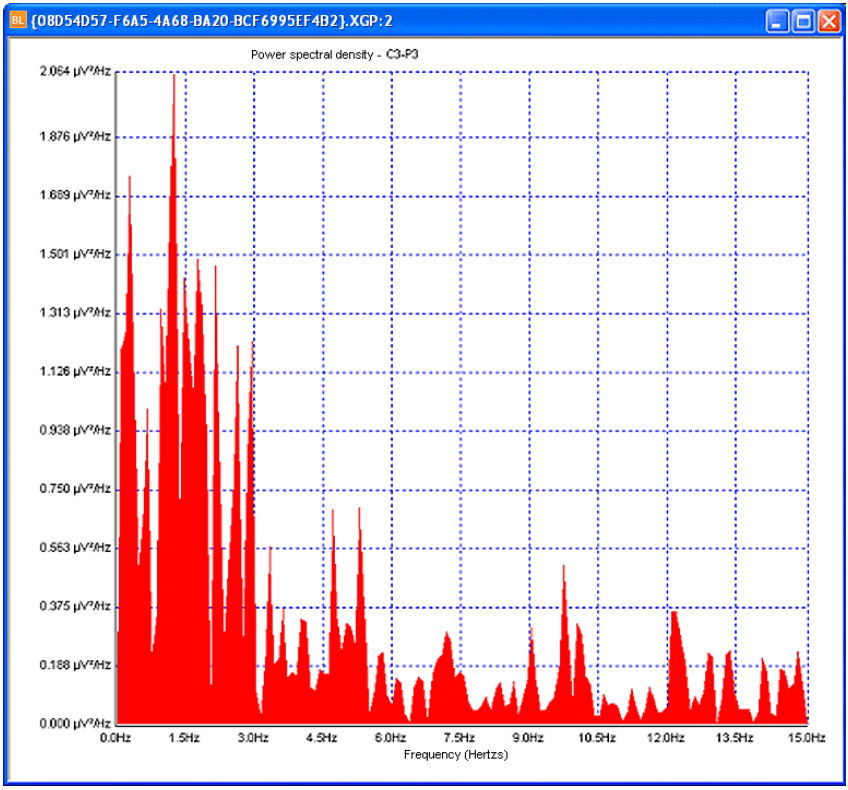
In the waveform window, choose the part of the test from which you wish to obtain the frequency spectrum.

The contextual menu of the selection will appear. Click on *Frequency spectrum*.

The program will ask for the channel for which to show the frequency spectrum. Select the channel and click on *Accept*.

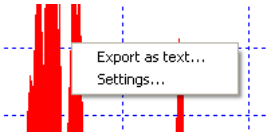
Selection of channel for FFT
Select among the following visible channels the one from which you want to obtain its frequency spectrum.
Ch8: EEG C3-01
OK
Cancel

A new window will open with the frequency spectrum graph or the power spectral density. The frequencies between 0 and 50 Hz will appear on the horizontal axis. The power for each of the frequencies will appear on the vertical axis.



6.1.2 MODIFYING THE FREQUENCY SCALE

Right click on any part of the graph and select *Properties.*



In the *Graph properties* window, select the range of frequencies you wish to view and click on *Accept* to apply the changes.

6.1.3 PRINTING THE FREQUENCY SPECTRUM GRAPH

Make sure that the frequency spectrum graph is enables and go to *File > Print.*

Choose the printer, printer properties, printing interval and number of copies.

Click on *Accept* to start printing.

6.1.4 EXPORTING FREQUENCY SPECTRUM DATA

The frequency spectrum data can be exported to a text file:

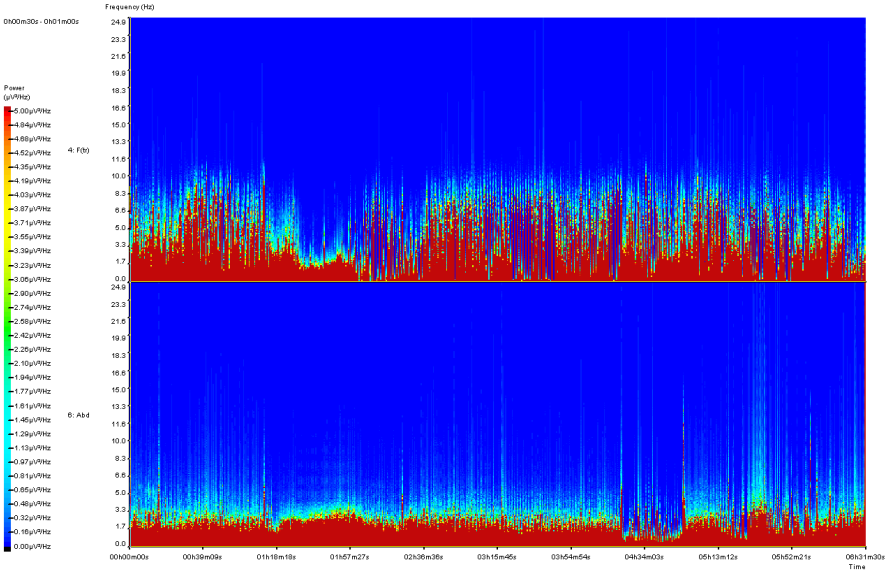
Right click on the frequency spectrum graph. Choose *Export as text* in the contextual menu.

Enter a name in the *Save as* dialog for the file that will contain the exported data.

6.2 THE POWER/FREQUENCY/TIME GRAPH

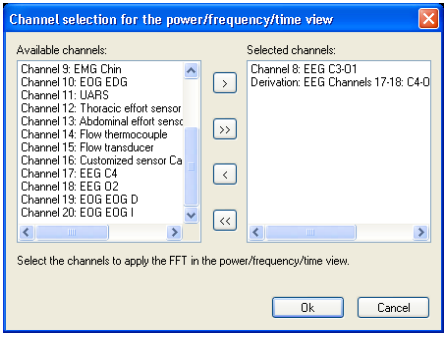
6.2.1 DISPLAYING THE POWER/FREQUENCY/TIME GRAPH

For each channel selected, the power/frequency/time graph shows the power contained in each frequency throughout the test. This graphic display of the test allows the user to easily detect different events, such as apneas or hypopneas, spindles, K-complexes or REM stages, and is therefore a tool that helps the user evaluate the test. The range of frequencies analyzed goes from 0 to 25 Hz, although it can also be divided into characteristic frequency bands (alpha, beta, delta, theta).

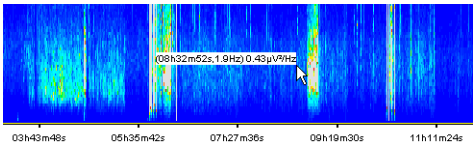


Choose *Graph power/frequency/time* in the *See* menu or use the button in the toolbar.

The program will ask for the channels to display in the graph.


Channel selection for the power/frequency/time view
Available channels:
Channel 9: EMG Chin
Channel 10: EOG EOG
Channel 11: UARS
Channel 12: Thoracic effort sensor
Channel 13: Abdominal effort sensc
Channel 14: Flow thermocouple
Channel 15: Flow transducer
Channel 16: Customized sensor Ca
Channel 17: EEG C4
Channel 18: EEG O2
Channel 19: EOG EOG D
Channel 20: EOG EOG I
Selected channels:
Channel 8: EEG C3-O1
Derivation: EEG Channels 17-18: C4-O
Select the channels to apply the FFT in the power/frequency/time view.
Ok
Cancel

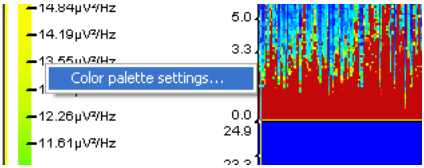
After the FFT has been calculated, the *power/frequency/time* graph will appear. If the user places the cursor over any point of the graph and right clicks, he will obtain the power for the channel, frequency and time instant where the cursor is positioned.



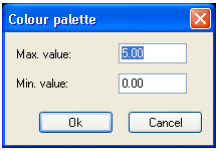
6.2.2 MODIFYING THE COLOR SCALE

By default, the program automatically adjust the color scale taking into account the highest power found. However, the color scale can be easily modified.

Right click on the color scale. In the menu that appears select *Color palette options.*

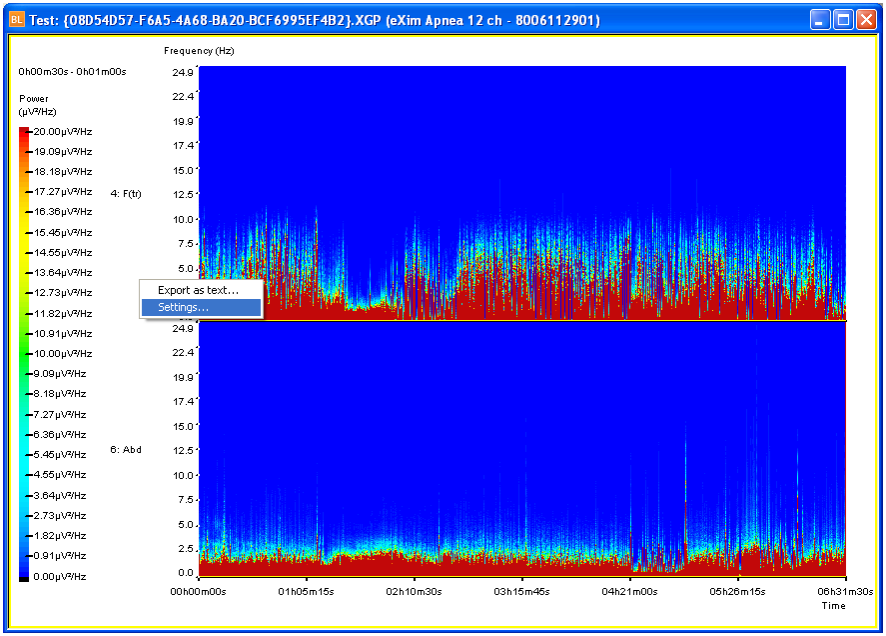


In *Color palette options* select the maximum and minimum values for the graph scale. Click on *Accept* to apply the changes.



6.2.3 CHANGING THE FREQUENCY SCALE

Right click on any part of the graph and select *Properties.*



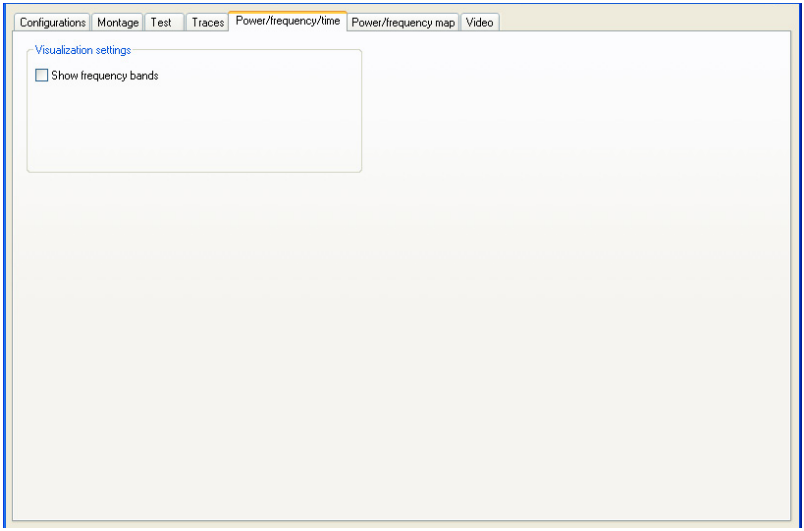
In the *Graph properties* window, select the range of frequencies you wish to view and click on *Accept* to apply the changes.

6.2.4 SHOWING THE GROUPED FREQUENCIES BY FREQUENCY BANDS

Open the *Viewing options* window from the *Analysis* menu > *Viewing options*.

Enable *Power/frequency/time*.

Enable *See frequency bands*.



Click on *Accept* to close the window and apply the changes.

6.2.5 PRINTING THE POWER/FREQUENCY/TIME VIEW

Go to *File* > *Print.*

Choose the printer, printer properties, printing interval and number of copies.

Click on *Accept* to start printing.

7. BRAIN MAPPING

The optional brain mapping module transforms electroencephalographic signals into information about brain activity and displays the power in each frequency spatially.

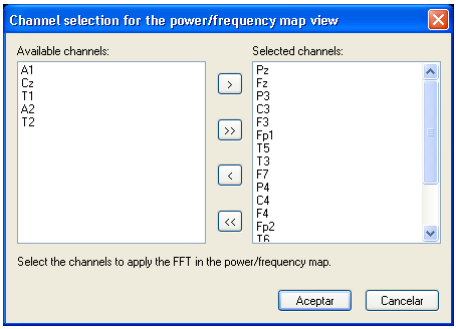
The functions describe throughout this chapter are only available if you have purchased the brain mapping license.

7.1 POWER/FREQUENCY MAP

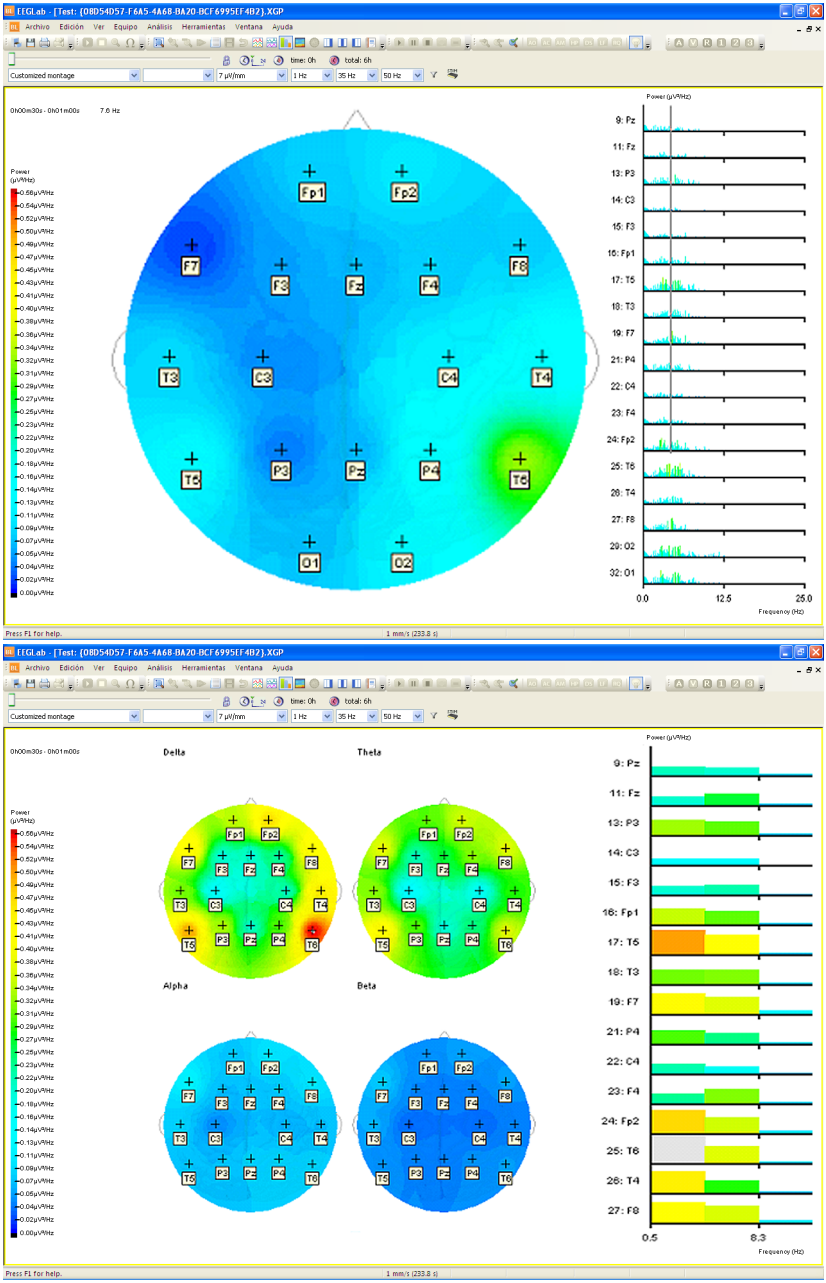
The power/frequency map is the graphic representation of brain mapping. It consists of a zenital view of the patient's head showing the standard 10-20 electrodes and the power contained in each point for the chosen frequency by means of a color scale. The right-hand area shows a graph of the power contained in each frequency for each channel. The data are calculated in 30-second epochs. Use the time bar to update the power/frequency map with the activity of a specific time instant.

Choose *Power/frequency map* in the *See* menu or click on the button in the toolbar.

The program will request which electrodes to show in the map to calculate the FFT.



After the FFT has been calculated, the power/frequency map will appear.


EEGLab - [Test: {08D54D57-F6A5-4A68-BA20-BCF6995EF4B2}.XGP
Archivo Edición Ver Equipo Análisis Herramientas Ventana Ayuda
Customized montage
Power (μV²/Hz)
Fp1 Fp2 F7 F3 Fz F4 F8 T3 C3 C4 T4 T5 P3 Pz P4 T6 O1 O2
9: Pz
11: Fz
13: P3
14: C3
15: F3
16: Fp1
17: T5
18: T3
19: F7
21: P4
22: C4
23: F4
24: Fp2
25: T6
26: T4
27: F8
29: O2
32: O1
0.0
12.5
25.0
Frequency (Hz)
Press F1 for help.
Delta
Theta
Alpha
Beta
0.5
8.3

7.2 CHANGING THE VISIBLE FREQUENCY IN THE MAP

The frequency being viewed in the map is shown at the top left of the graph. To change it, double click on the desired frequency in the power/frequency graph on the right. The frequency can also be changed from *Viewing options*:

Go to *Analysis* > *Viewing options*.

Enable *Power/frequency map*.

In the default *Frequency* text box enter the frequency that you wish to see in the map.

Click on *Accept* to apply the changes.

7.3 CHANGING THE POWER/FREQUENCY MAP OPTIONS

Open *Viewing options* from the *Analysis* menu > *Viewing options*.

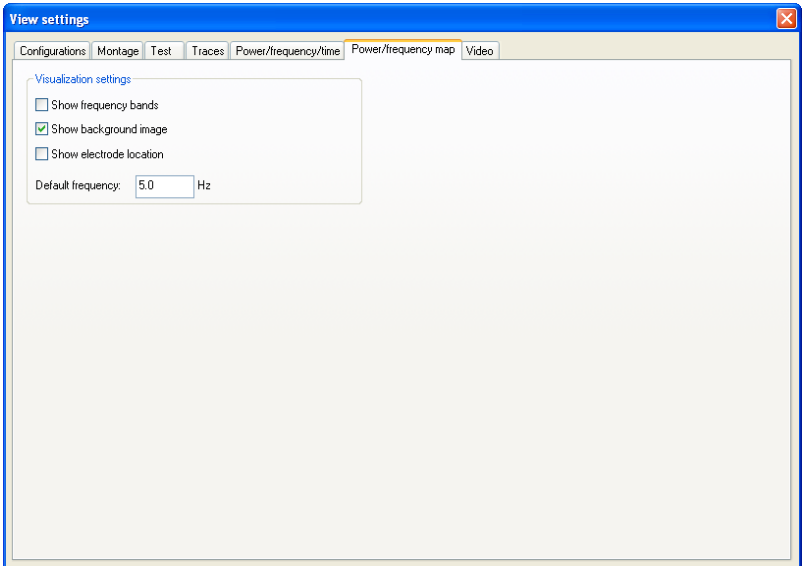
Enable *Power/frequency map*.

Enable *See frequency bands* to group the frequencies in characteristic band: alpha, beta, delta, theta.

Enable *See background image* to show a brain image in the map headers.

Use *See electrode sites* to show or hide the names and position of the electrodes selected in the map view.

Click on *Accept* to close *Viewing options* and apply the changes.


View settings
Configurations
Montage
Test
Traces
Power/frequency/time
Power/frequency map
Video
Visualization settings
Show frequency bands
Show background image
Show electrode location
Default frequency:
5.0
Hz

ANNEX 1. APPLICABLE STANDARDS

TheBitmedLab software has the CE Marking (CE 0197). The CE mark is a statement that the BitmedLab software fulfills the guidelines established by the EU for medical devices.

The BitmedLab is manufactured by SIBEL and the software meets the following standards and regulations:

Recommendations:

- National consensus document on the apnea-hypopnea syndrome (SAHS). Spanish Sleep Group (GES), September 2005.
- The AASM Manual for the Scoring of Sleep and Associated Events, 2007

European Directive 93/42/EEC:

- CE marking Class II a

Software:

- EN 62304:2006+AC:2008 Medical device software - Software life-cycle processes

Usability:

- EN 62366:2008 Medical Devices – Application of usability engineering to medical devices

Safety:

- EN 60601-1:2006+AC:2010: Electrical safety (3rd edition).

Pulse oximetry:

- ISO 80601-2-61 Special requirements for basic safety and essential operation characteristics of pulse oximeters for medical use

Symbology:

- EN ISO 15223-1:2012 Symbols to be used with medical device labels, labelling and information to be supplied.

- **Information supplied by the manufacturer:**

- EN 1041:2008 Information supplied by the manufacturer of medical devices

System quality:

- Manufactured according to the SIBEL S.A. Quality Manual, which is compliant with EN ISO 13485:2012+AC:2012 and EN ISO 9001:2008

Risk Management:

- EN ISO 14971:2012

The user should follow:

- Data protection: Data Protection Law and Directive 95/46/EC

ANNEX 2. COMPLIANCE WITH THE DATA PROTECTION ACT. DIRECTIVE 95/46/EC

This section aims to facilitate the compliance of current legislation referring to data protection by the user with the use of this software. (Consult your local translation of the 95/46/EC directive).

A brief description of the fundamental points of the aforementioned legislation is given, as well as what needs to be done with the BitmedLab Software and/or the operating system in order to comply with the requirements described in the aforementioned law.

According to current legislation, the software user, is solely responsible for the storage and treatment of their patient data in accordance with the law.

Observance of the recommendations included in this section does not guarantee, in any case, the full adaptation of user activity to the standards relating to data protection.

Requirements which specifically affect the use of the BitmedLab Software

Identification and Authentication

The processes for user identification and authentication for use of the BitmedLab are performed by the PC's operating system. Therefore only Windows Operating Systems allowing these processes in a secure way are valid, i.e. Windows XP, Windows Vista, Windows 7 and Windows 8 with an NTFS file structure. Windows 9x systems or FAT file structures are not valid.

The PC administrator must create a unique and personalized identification for each user and activate authorization verification. The operating system saves the passwords in an unintelligible way.

Access control

The Operating System must be configured to control the access to data, i.e. permit or deny access to data. Likewise, the PC administrator must set up the user account lock in order to impede reiterated attempts for unauthorized access. Consult the manual of the operating system in order to set up these system access

controls.

Access register

Accesses to the different databases are stored in one access register file.

Back-up copies (back-up and recovery)

The user must, at least once a week, make back-up copies of all data in order to guarantee full recovery of data in the case of a computer system failure. In the case of the BitmedLab software, full recovery of all database data is guaranteed if all of the application folder is saved, as well as the folder where the tests and reports are stored (by default the *BitmedLab tests* folder in *My documents*).

The back-up copy must be stored at all times in a different place from where the software is used.

Operating System Configuration

On a Windows operating system level (XP, Vista, 7 or 8) and for NTFS partitions, it is possible to restrict the access to the different databases using the security characteristics of the file system. Generally speaking, the control of access to databases is covered by the following points:

- Configuration of identification, authentication

  Each user that accesses the system must have a unique username and password, whether a local user or a network user connecting to a domain. The passwords must be changed epochically with a freely selected frequency and, whilst a series of passwords remain valid, they will be stored in an unintelligible way.

  User definition can be carried out from the Users and Passwords icon on the Control Panel. Using the Advanced Administration button on the Advanced Options tab you can access the Local and Group Users configuration. From the Users branch, new users can be created or existing properties modified. The access level of users can be set up in user properties on the Users tab of the Users and Passwords icon. We recommend that users are not given Administrator access level. In any event, the

Administrator is the person responsible for ensuring that users use their identification in the ways determined both technically and by documentation, as well as making them aware of their obligations in relation to the treatment of personal data.

It is also advisable to activate the security audit in order to register valid and erroneous accesses to the system.

- Access configuration and control. File permissions

  The following step is to set up the access levels to the files which form the databases in relation to the previous users. The database root can be found in the <BITMEDLAB_HOME>\ data directory. Inside, there is a register file «log» BITMEDLAB. log. One possible configuration is to provide full access to the <BITMEDLAB_HOME>\data folder to all users (or at least to the application users). In any case, the owner must always have read and write permissions on his database. The rest of the users may have no permissions on that database, for example. It must be taken into account that in this situation the users may only access their database from the application. On the log file BITMEDALAB.log level, it would be advisable for the users to only have read access so that the application could register the accesses to the different databases.

  Permissions can be applied from Windows Explorer itself. Simply access the Properties of the folder or file you wish to change permissions and select the Security tab. From this tab you can select both the users who may access and the permissions (total control, read, modification, write, etc.) of each user.

- File audit.

  We recommend the activation of the log file audit in order to register on the security event viewer the actions performed upon it.

  To activate this option, you must first enable the audit of the aforementioned file. At this level, you must specify the users (according to the users which access the <BITMEDLAB_ HOME>\data directory) and types of access to be audited. The log file audit can be activated from the Security tab of the file Properties. Using the Advanced button you can access the Audit tab. From here, simply add the users and the type of

access to be audited. It must be taken into account that if all actions on the log file are audited, the security events viewer will have many entries and will complicate the monitoring of unauthorized accesses.

The next stop is to activate the audit of access to objects in the local security configuration. To do so, access the Administrative Tools icon from the Control Panel. Once there, you must select the Local Security Directive and the Local Directives branch from the directives. You must then access Audit Access to Objects. Both correct and erroneous accesses can be enabled.

Finally, the folder where the test and report files are stored may also be audited (usually My documents\BitmedLab tests).

Access register description

Access to the different databases is stored on the one log file (BITMEDLAB.log) in the folder where the application is installed (by default C:\Program Files\Bitmed\BitmedLab x.x and from now on <BITMEDLAB_HOME>\data).

This file is created the first time that the application is executed and cannot be deactivated The system administrator is responsible for the maintenance of said file with regard to size, and the preparation of a monthly report where the epochic reviews carried out are analyzed and any problems detected are reported, should there be any.

The log file saves for each line:

- User
- Time and date of access
- Database accessed
- Action carried out on the database
- Type of access (authorized or denied)
- File path of database accessed
- Reference of the register accessed

The format of each of the lines is the following:

[USER], [YYYYMMDD HH:MM:SS], [BASE], [ACTION], [ACCESS], [PATH], [REFERENCE]

The actions to be registered are divided into:

• Action on the actual database itself (open, close, delete, etc.)

• Action on the registers stored on the database (insert, consult, delete, etc.)

In any case, the register or access control «log» file, must be kept for a minimum epoch of two years.

Below, all actions registered on the log file are listed:

- Open DB
- Close DB
- Select DB
- Create DB
- Delete DB
- Modify the access password
- Consult record
- Consult all records
- Add record
- Update record
- Delete record
- Export record
- Import record

Other important issues

- Printing documents:

  In the case of storage of paper prints containing patient details, it is required that these documents remain duly safeguarded in such a way that only duly authorized personnel have access to them. Likewise, in the case of a user deciding to dispose the printed documents, it will be necessary to ensure their effective physical destruction in order to avoid unauthorized access to the data.

- Exporting tests

  Once the test has been exported to a file, the software user is responsible for the security of said file, and its later deletion.

- Data transmission:

  The software permits the transmission of files with patient data via the internet. If this functionality is used, the user must configure their e-mail server so that the data is encrypted before transmission and is therefore converted into unintelligible data for any unauthorized access.

ANNEX 3. HOTKEYS

Insert note	Insert
Delete selected waveforms	Delete
Increase amplitude of selected waveforms	Up arrow
Decrease amplitude of selected waveforms	Down arrow
Start/pause playback	Ctrl + Espace
Select epoch for printing	Alt + P
Select all waveforms	Ctrl + Tab
Deselect all waveforms	Escape
Increase time per epoch x2	-
Decrease time per epoch x2	+
Insert navigation anchor	Ctrl + M
Move to the navigation anchor	Ctrl + N
Move to the start of the test	Home
Move to the end of the test	End
Move to the previous epoch	Page up
Move to the next epoch	Page down
Move one second back	Left arrow
Move one second forward	Right arrow
Move half an epoch forward	Tab
Change the way text of waveforms is displayed	C
Change the way text of event marks is displayed	E

ANNEX 4. BITMEDLAB SPECIFICATIONS

Useful life	7 years
Available data or graphs in the report	Pulse rate, SpO_2 and body position summary graphs Sleep events summary graph Time in each body position Mean and maximum duration for each sleep event Apnea-hypopnea index Indexes of all sleep events Indexes of sleep events by body position Pulse rate and SpO_2 histograms PTT increases; decreases; mean, minimum and maximum PTT values Hypnogram Sleep stages stats
Supported events (events supported by the automatic analysis module are marked with *)	Apnea (obstructive, central and mixed) * Hypopnea * Desaturation * Limb movement * Periodic limb movement (PLM) * Snore * Arousal * Movement arousal Respiratory effort related arousal (RERA) * Flow limitation Bruxism Periodic respiration Cheyne-Stokes respiration Undetermined respiratory event Tachycardia * Bradycardia *

PC requirements		Required	Recommend.
	Operating system	MS Windows XP, Vista or 7	
	CPU	Intel Pentium 4, AMD Athlon	Dual core processor
	RAM memory	1024 Mb	2048 Mb
	Free HD space	100 Mb	Several gigabytes are needed to acquire synchronized digital video
	USB 1.1 ports	Screen&Go/ Sleep&Go: 2 (if a Bluetooth module and card reader are used) eXea: 1	
	Screen resolution	1024 x 768	1280 x 1024 or higher
	Synchronized digital video capture	Free PCI Xpress slot (Desktop PCs) Free Xpress Card slot (Laptops)	
User-defined Screen&Go and Sleep&Go configurations	Unlimited in the software, up to 10 configurations at the same time in the device		
Scheduled tests	Unlimited in the software, up to 5 scheduled tests at the same time in the device		
User-defined montages	Unlimited		
Database	Stores patients' data, tests and reports		
Customizable on screen time	5, 6, 7, 8, 9, 10, 15, 20, 30, 60, 120, 300 seconds or user-defined		

Filters	Low pass filter: 3, 5, 10, 15, 25, 35, 45, 70, 100 Hz High pass filter: 0.1, 0.5, 1, 2, 10 Hz
Environmental conditions for the CD-ROM	Transportation and storage: see NOTE (*) at the end of table Temperature: -25ºC to +70ºC Relative humidity: <93% (without condensation)
Other features	Annotations on the test Customizable channel amplitudes Customizable thickness of waveforms Values over the waveforms Trends window Customizable reports Digital video capture Spectral analysis module Sleep events detection module Sleep stages detection module

(*) It is recommended to store the CD ROM at 25ºC. At this temperature the manufacturers guarantee 1.000.000h. At 70 ° C the life is reduced to 2.000 h. See specifications of CD ROM for more information.

The screen resolution specifications are recommended for a comfortable use of the system while reviewing the studies. Take into consideration the applicable regulations in terms of occupational safety.

ANNEX 5. SYMBOLS

	MANUFACTURER (MANUFACTURER'S NAME AND ADDRESS)
	MANUFACTURING DATE
	TEMPERATURE LIMITATION
	WARNING

ANNEX 6. MAINTENANCE

The BitmedLab software does not require any specific maintenance, except that for any computer program handling information.

- Make a copy in a CDROM in case the original gets damaged.
- Make periodical backup copies of the Data Base, test files and report files, in order to be able to restore them if any loss of information occurs in the computer.

The software is improving continuously. Therefore, contact regularly with the Technical Assistance Service at SIBEL, S.A. to get the latest updates.

If any problem, doubt or suggestion arises while using the product or if you require additional training, please follow the next steps:

1 Use the help windows available in the program
2 Use this User's Manual properly
3 Check that you have the latest version installed
4 Contact with the After Sales Service of SIBEL S.A. at

You can also check the "Known abnormalities report" (534-741-MU2) available to the user from SIBEL S.A.

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